

# **OFFICE OF ADOLESCENT HEALTH**

## **GUIDANCE FOR PREPARING THE YEAR FOUR NON-COMPETING CONTINUATION GRANT APPLICATION**

*Teenage Pregnancy Prevention Grantees*



**Applications Due: May 31, 2013**

Office of Adolescent Health

GUIDANCE FOR PREPARING THE YEAR FOUR NON-COMPETING CONTINUATION  
GRANT APPLICATION

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**Office of Adolescent Health**  
**GUIDANCE FOR PREPARING THE YEAR FOUR NON-COMPETING**  
**CONTINUATION GRANT APPLICATION**

**PART ONE: GENERAL INSTRUCTIONS**

Eligibility

These instructions are applicable to existing Office of Adolescent Health Teenage Pregnancy Prevention grantees and provide guidance on the preparation and submission of the Year Four non-competing continuation grant application. This continuation announcement is subject to the appropriation of funds. The actual amount available will not be determined until enactment of the FY 2013 federal budget.

Purpose

The purpose of a non-competing continuation grant application is to:

- Report on the progress of the project during the current budget year.
- Provide a work plan (inclusive of program and evaluation activities) for the upcoming budget year.
- Provide a detailed budget and budget narrative justification for the upcoming year.

Each section of the continuation application should justify and support the other sections. The Exhibits included in this Guidance offer examples of how to provide the required information in a clear and succinct way.

The OAH Guidance for Preparing the Year Four Non-Competing Continuation Grant Application prescribes the content, information, and data requirements for OAH non-competing grant applications. This guidance should be used in conjunction with the Funding Opportunity Announcement (FOA) under which the competing grant application was funded and any other application materials provided by the Office of Grants Management or posted at GrantsSolutions.gov in the non-competing application kit. The FOA provides information and guidance for grantees for the entire project period.

Non-competing continuation grant applications will be reviewed by the OAH Project Officer and the OASH Office of Grants Management Grants Management Specialist. The application must provide detailed information on the progress in accomplishing goals and objectives during the first six months of the current budget year; a detailed work plan that outlines the goals, objectives, and activities for the upcoming budget year; TPP performance measure data; evaluation progress reporting; and a detailed budget and budget justification for the upcoming budget year. Carryover requests should not be included in non-competing continuation grant applications.

## **PART TWO: NON-COMPETING APPLICATION PREPARATION AND SUBMISSION**

### Application Submission

The Office of the Assistant Secretary for Health (OASH) provides grantees with the ability to submit non-competing continuation applications electronically via GrantSolutions.gov. Applicants will receive notification from GrantSolutions.gov via email confirmation receipt. Hard copy application submissions are no longer accepted by the OASH Office of Grants Management.

Any applications submitted via any other means of electronic communication, including facsimile or electronic mail, will not be accepted for review. Grantees are encouraged to initiate electronic applications early in the application development process, and to submit early on or before the due date. This will aid in addressing any problems with submission prior to the application deadline.

Applications must be received by **Friday, May 31, 2013 at 11:00 p.m. Eastern Standard Time**. Applications submitted electronically to GrantSolutions.gov after the deadline will not be accepted for review.

Your non-competing continuation application kit can be found in GrantSolutions.gov. If you encounter any difficulties submitting your non-competing continuation grant application through GrantSolutions.gov, please contact the GrantSolutions helpdesk at (866) 577-0771 or [App\\_Support@ACF.HHS.GOV](mailto:App_Support@ACF.HHS.GOV) prior to the submission deadline. If you need further information regarding the application process, please contact your Grants Management Specialist. For programmatic information, please contact your OAH Project Officer.

### **Electronic Submissions via the GrantSolutions System**

Electronic applications submitted via the GrantSolutions system must contain all completed online forms required by the application kit, the Project Narrative, Budget Information and any appendices. Electronic non-competing continuation grant application submissions must be submitted no later than 11:00 p.m. Eastern Standard Time May 31, 2013. Grantees are now required to print out, sign and upload page three (3) of the SF 424 Application for Federal assistance, page two (2) of SF 424B Assurance form and SF –LLL Disclosure of Lobbying Activities. Only the signature page is required when uploading with original signature.

Non-competing continuation grant applications will not be considered valid until all electronic application components are received by the OASH Office of Grants Management according to the deadlines specified above. Upon completion of a successful electronic application submission, the GrantSolutions system will provide the grantee with a confirmation page indicating the date and time (Eastern Standard Time) of the electronic application submission. This confirmation page will also provide a listing of all items that constitute the final application submission including all electronic application components.

As items are received by the OASH Office of Grants Management, the electronic non-competing application status will be updated to reflect receipt of the items. It is recommended that the grantee monitor the status of their application in GrantSolutions to ensure all items are received.

### **PART THREE: NON-COMPETING APPLICATION CONTENT**

The non-competing continuation grant application should include the required OASH grants management forms, a table of contents, project narrative that includes both a progress report for the first six months of the current project period and a work plan for the upcoming budget year, TPP performance measure data submission, evaluation progress report, detailed budget narrative and budget justification for the upcoming budget year, and any additional materials in the appendices. The contents of the application should be properly labeled and numbered. Contents should be complete and written in 12-point font.

Adherence to the following guidelines will facilitate the review of the non-competing continuation application and will ensure that the required components are submitted. Non-competing continuation application narratives are evaluated on the basis of substance, not length. Cross-referencing should be used rather than repetition.

#### **I. REQUIRED FORMS AND OTHER REQUIRED INFORMATION**

Table 1 below lists the required forms and other information that must be submitted within this section of the non-competing application.

**Table 1**

<b>Form</b>	<b>Required for Non-Competing Continuation Grant Applications</b>	<b>Source of Form</b>
SF-424, Application for Federal Assistance	✓	Non-competing continuation application kit at <a href="http://www.grantsolutions.gov">www.grantsolutions.gov</a> - <b>Upload pg 3 with signature</b>
SF-424A, Budget Information Non-Construction Program	✓	Non-competing continuation application kit at <a href="http://www.grantsolutions.gov">www.grantsolutions.gov</a>
SF-424B, Assurances Non-Construction Program	✓	Non-competing continuation application kit at <a href="http://www.grantsolutions.gov">www.grantsolutions.gov</a> - <b>Upload pg 2 with signature</b>
SF-LLL, Disclosure of Lobbying Activities	✓	Non-competing continuation application kit at <a href="http://www.grantsolutions.gov">www.grantsolutions.gov</a> - <b>Upload with signature</b>

## **II. TABLE OF CONTENTS**

A Table of Contents outlining the components of the application is required and will provide assurance that all required sections of the non-competing continuation grant application have been included.

## **III. PROJECT NARRATIVE**

The Project Narrative must include the following:

- A. Six-month Progress Report:** Describes the completion of objectives and activities during the first six months of the current budget period as reflected in the Notice of Grant Award (September 1, 2012 – February 28, 2013).
- B. Year Four Work plan:** Describes the goals, objectives, activities, timeline, person/agency responsible for accomplishing each activity, and the measures of effectiveness for each objective for the next budget year (September 1, 2013 – August 31, 2014).

### **A. Six-Month Progress Report**

The six-month progress report should describe the completion of objectives and activities during the first six months of the current budget period as reflected in the Notice of Grant Award (September 1, 2012 – February 28, 2013).

The progress report is a mechanism through which grantees detail their accomplishments and activities over the first six months of the current budget period. All goals, objectives, and activities identified in the six-month progress report should be clearly connected. Each activity identified and described should directly support a corresponding objective. The progress report should include a thorough description of all objectives and activities to support the grant program, including those focused on project management, program implementation, and evaluation.

In order to appropriately document the progress of the grant, the progress report should include explanations for each objective and activity identified. Explanations for achieving or not achieving the identified objective or activity should include supportive statements. Descriptions supporting the accomplishment of the objective or activity should provide more information than a “yes” or “no” response.

The progress report should:

- Describe the status (met, ongoing, or unmet) of each objective and activity in the current year’s work plan.
- Provide a narrative describing what has been done to work toward accomplishing the objectives and completing the planned activities (include any outcomes to date).
- Describe any barriers encountered, and how the barriers were addressed.
- If applicable, include the reasons that goals or objectives were not met and a discussion of assistance needed to resolve the situation.

- Report on any other significant project activities, accomplishments, setbacks or modifications (e.g., change in key staff, change in scope) that have occurred during the six-month reporting period and were not part of the program work plan. These should include legislative and/or judicial actions impacting the program, as well as agency events.

**Exhibit F** provides a checklist of key information that should be included in the progress report. The items listed in the checklist represent required activities as stated in the funding announcement. Ultimately, the progress report should be specific to your program and should provide a thorough update on the status of your program objectives and activities completed during the six-month period. The checklist provides guidance on the minimum activities that should be included in the progress report, but is not exhaustive.

The narrative included in your progress report should be detailed and supporting documents (included as Appendices) should be included if they add clarity or depth, substantiate the narrative, and/or present information succinctly. Extensive appendices are not required. Six-month progress reports are evaluated on the basis of substance, not length. Cross-referencing should be used rather than repetition.

See **Exhibit A** for an example of a Six-Month Progress Report Template.

See **Exhibit B** for an example of a partially completed Six-Month Progress Report.

See **Exhibit F** for the Continuation Application Checklist with a list of key information to include in the progress report.

## **B. Year Four Work plan**

The work plan for Year Four (September 1, 2013 – August 31, 2014) should include the long-term goals that span the life of the five-year grant program, as well as the objectives and activities that will be completed during year three to assist in achieving the long-term goals. Programmatic efforts outlined in the work plan must align with the guidance included in the original Funding Opportunity Announcement, available at <http://www.hhs.gov/ash/oah/grants/closed-grants.html>.

The work plan should include both program-specific and evaluation-specific objectives and activities. All objectives should be SMART (specific, measurable, achievable, realistic, and time-phased). More information on writing SMART objectives is available at: <http://www.cdc.gov/healthyyouth/evaluation/pdf/brief3b.pdf>.

For each objective:

- Provide a rationale for the objective;
- List the activities that will be implemented to accomplish the objective;
- Provide a timeline for accomplishing each activity;
- Identify the person/agency responsible for completing each activity; and
- Identify how you will assess the achievement of the activity.

The approved work plan is intended to be an ongoing monitoring and evaluation tool for both the grantee and the Office of Adolescent Health to use throughout the approved project period.



**Exhibit F** provides a checklist of key information that should be included in the work plan. The items listed in the checklist represent required activities as stated in the funding announcement. Ultimately, the work plan should be specific to your program and should provide a thorough description of the objectives and activities planned for year four. The checklist provides guidance on the minimum activities that should be included in the work plan, but is not exhaustive.

Please note, beginning in Year Four, grantee progress report and performance measure data will be due 30 days after the end of the reporting period. The six-month progress report and performance measure data will be due on March 29, 2014 and the twelve-month progress report and performance measure data will be due on September 30, 2014. The Year Five continuation application will continue to be due on May 31, 2014, but will no longer include the progress report and performance measure data. OAH will provide grantees with guidance prior to each reporting due date.

See **Exhibits C & D** for examples of Work plan Templates.

See **Exhibit E** for an example of a partially completed Work plan.

See **Exhibit F** for the Continuation Application Checklist with a list of key information to include in the work plan.

#### **IV. TPP PERFORMANCE MEASURE REPORTING**

All grantees are required to submit their performance measure data at the same time as they submit their progress reports. Performance measure data for the period from September 1, 2012 to February 28, 2013 should be submitted with the Year Four continuation application.

This document provides guidance regarding TPP Performance Measure Reporting Requirements. A summary of all of the measures is provided in Exhibit G in the Appendix. Data are to be reported by grantees and their evaluators using the TPP Performance Measures Website (<https://tpp.rti.org>). Data are of two main types: grantee-level data and participant-level data. Data will be entered using one of two options:

- Option 1: Reporting raw data directly into the web system,
- Option 2: Uploading raw data by means of spreadsheets using pre-defined variables

All participant-level data (demographics and behavior and intention measures) will be reported at the participant level, using either option 1 or option 2, as described above. All measures are described in detail later in this document.

##### Performance Measures Website

The TPP Performance Measures Website is located at <https://tpp.rti.org>. **Detailed instructions for reporting performance measures are provided in the TPP Performance Measures Manual.** Links to the manual and recordings and transcripts of webinar trainings are located on the home page of the website as well as on the resources page. You can also access recordings of the performance measures webinars through the OAH website.

A Help Desk is also available if additional assistance is needed. To contact the Help Desk, click on the Help Desk tab at the top of the TPP/PREIS Performance Measures Website (after logging on), and you will be able to contact our webmaster regarding your issue. When reporting your problem, please be as descriptive as possible by including the page on which the problem was encountered as well as steps that could be used to replicate the issue. In addition, please provide the name of your grantee organization along with your name and email address and telephone number.

Questions can also be emailed using one of the links:

[Tier1CD-Feedback@rti.org](mailto:Tier1CD-Feedback@rti.org)

[Tier2PREIS-Feedback@rti.org](mailto:Tier2PREIS-Feedback@rti.org)

[Tier1AB-Feedback@rti.org](mailto:Tier1AB-Feedback@rti.org)

### Performance Measures

The TPP performance measures are collected at both the grantee and the participant level.

Altogether, there are three broad types of measures:

- grantee-level measures about program structure;
- grantee-level measures about program implementation; and
- participant-level measures about outcomes.

#### I. Grantee-Level Measures about Program Structure

There are four groups of measures that address program structure: reach, partners, training, and dissemination.

1. **Reach** is defined as the number of participants who are enrolled in the program and receive at least one session. It includes participants who do not have permission to be in the evaluation but nevertheless receive the program. Reach does not include control group youth. The number of youth served may be different than the number with participant-level data, such as measures of behavior. Youth participants are counted separately from any other individuals served (e.g., parents). Reach data are collected from all grantees.

These data are to be reported by demographic characteristics, age, grade, ethnicity, race and language spoken at home all by gender. In addition, other participants are reported by type (i.e., parents or other) (see Exhibit G in the Appendix).

Data are to be taken from enrollment statistics and may be entered using option 1 or option 2. Please mark “*unknown/not reported*” for any participants who answered “*other*” for race.

2. **Partners** are those organizations that are working with the grantee but not part of the grantee organization per se, such as a school system, a clinic, or another program. Grantees will need to report how many partners they started with at the beginning of the reporting period and how many remained at the end of the reporting period.

The first performance measure regarding partners concerns the number of partners grantees are working with. The second performance measure regarding partners concerns retention. All grantees need to enter this data directly onto the website.

3. **Training** measures both the number of facilitators who are newly trained and the number who receive follow-up training. It includes not only training or re-training on the curriculum used, but any topic that will improve the facilitators' delivery of the program. For instance, training on topics such as adolescent development, classroom management strategies, or techniques used to retain youth in programs would provide information that would enhance the skills of facilitators and would be counted here. Training may be given by the grantee or a partner. All grantees need to report these measures.

There are two questions that are asked of all grantees. Responses to both questions are entered directly into the website.

4. **Dissemination** measures the number of manuscripts and presentations that were disseminated during the reporting period. For Tier 2 and PREIS grantees, there is an additional measure on the progress on packaging their programs for replication.

All of this information is reported directly on the website by all grantees. The manuscripts and presentations should be related to work that was developed as a result of having grant funding through the TPP/PREIS grant such as experiences in implementing the program, lessons learned, or evaluation results.

For questions about the packaging of their programs for replication, all Tier 2 and PREIS grantees will indicate whether the following pieces of their program have been completed and approved: logic model, core components, fidelity monitoring tools, curriculum manual, facilitator manual, training materials, and adaptation guidance. During each reporting period, each Tier 2 and PREIS grantee needs to indicate which pieces have been completed, but they only need report a completed piece once. This information is reported directly on the website.

## II. Grantee-Level Program Implementation

Fidelity and Dosage are two different facets of program implementation that are to be reported by every grantee. There are several different measures of each and there are several different ways that the data may be reported.

1. **Dosage** provides an indication of “how much” of the program a participant received and is tracked through attendance. The performance measures that will be calculated from the attendance data are the mean and median percentages of program services received by youth and other participants such as parents (if applicable), and the percentages of youth and others (if applicable) who received at least 75% of the program. The measures will be reported to OAH by age and gender.

Attendance data must be reported for each session in which the curriculum is implemented. These data are tracked at the individual level. Complete instructions regarding how to enter these data on the website or upload the information via spreadsheets are provided in the TPP Performance Measures Manual. These data are to be reported for youth and any other participants who are receiving the program. As with the measures for reach, dosage is collected on all youth who receive the program, even those who do not have parental permission to be in the evaluation.

This year we introduced a change to the TPP Performance Measures System that allows grantees to track the number of units a participant received of non-curriculum components. This is most helpful in tracking hours of Community Service Learning (CSLs). If your program utilizes CSLs, we advise recording the information following the example below.

- 1) Do not track CSLs by the date they occur. For each section that has a CSL, only create **one** CSL component **per reporting period**. The date you would use for this CSL should correspond to the last date of the reporting period and activities planned and completed should both be “1”.
  - 2) When your participants complete CSL hours (these can be fractional hours), update their attendance accordingly. What you enter will replace the existing value. Therefore, when you update their hours, add to the existing hours. For example, if they have 2 hours already logged and they completed an additional hour, then you would enter “3”. Also, be sure to mark that the participant attended (i.e. “Yes”).
  - 3) The next reporting period within the same section, you would create a new CSL component with the date of the end of that reporting period. Be sure to use a **UNIQUE** component name. You may do this by adding incremental to the end of the component name (e.g. CSL 1, CSL 2, CSL 3, etc.).
2. **Fidelity** addresses how well the implementation adhered to the program’s model. The fidelity performance measures are derived from the facilitators’ own assessment and from the ratings completed by an observer who is familiar with the program (for 10% of the sessions). An additional measure addresses whether there is a system in place to ensure fidelity. All grantees must report these measures<sup>1</sup>.

Facilitator measures include adherence to both the program-specified number of sessions and activities. All grantees will need to provide the mean and median number of sessions (across all sections and cohorts) completed in the reporting period. All grantees will also need to report the percentage of sessions that have a facilitator-completed fidelity monitoring log. These measures are to be reported by all grantees directly on the website.

*Facilitator measures.* Adherence to program-specified activities is to be tracked on fidelity monitoring logs and reported using one of the two options. Grantees need to report the number of activities planned and the number completed for each session during the reporting period. These data may be entered directly onto the website or uploaded using spreadsheets. When reporting, the session data are associated with the related class or section. Detailed instructions for entering adherence to program-specified activities on the website or uploading the data via spreadsheets is covered in the TPP Performance Measures Website Manual. The performance measures will be calculated by the system.

*Observer measures.* The fidelity performance measures that are obtained from the observer

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<sup>1</sup> There are a few grantees who have received exemptions from OAH because their program models did not lend themselves to the fidelity measures.

include (1) adherence to the program specified activities and (2) the quality of implementation. These data will be reported in a similar way to those from the facilitator. Adherence to program-specified activities is recorded on the same fidelity monitoring logs as the facilitator uses. Grantees will report the number of activities planned and the number completed for each session that is observed by either entering these values on the website or by uploading spread sheets. The system will calculate the relevant performance measures (mean, median, minimum and maximum percentages of activities completed).

The quality of implementation is recorded using the *Program Observation Form for TPP Grantees*, available on the OAH website at <http://www.hhs.gov/ash/oah/oah-initiatives/ta/performance-measures.html> as well as on the TPP/PREIS Performance Measures website (<https://tpp.rti.org>). This rating form is completed by the observer and covers various aspects of facilitators' delivery of the curriculum. The numerical rating scores will be used to report the quality. Observers are to complete these ratings for the all of the sessions that they are observing. Grantees who are using option 1 or 2 will report the scores on these items by either entering them directly on the website or uploading spreadsheets containing these scores. The system will compute the average rating per session and then the percentage of sessions that received a score of  $\geq 4$ .

The final fidelity performance measure assesses whether there is a system in place to ensure fidelity. This measure is derived from the *Fidelity Process Report Form*, available on the OAH website at <http://www.hhs.gov/ash/oah/oah-initiatives/ta/performance-measures.html> as well as on the TPP/PREIS Performance Measures website (<https://tpp.rti.org>). The grantee project director is to complete this form at the end of each project year. Grantees will enter their total score from the form on the website with the November 30<sup>th</sup> performance measure report.

### III. Participant-Level Outcomes

Participant-level outcome measures include measures of behaviors/intentions. The measures of behaviors and intentions are collected only for Tier 1 C/D, Tier 2, and PREIS participants, and for Tier 1 A/B participants who are in the federal evaluation (these will be collected by the federal evaluators). These data are collected from all youth who have received permission to be in the evaluation and are at least in the 7<sup>th</sup> grade. All participant-level data will need to be reported at the individual level under the "participant data" tab.

**Behaviors/Intentions** measures are only asked of youth who are in programs that are being rigorously evaluated (and youth who are in the control groups for those programs). All behaviors/intentions data will be reported by the grantee's evaluator and grantee program staff will not have access to the behaviors/intentions data. Measures of behaviors/intentions will be collected at baseline and at various points in time after the intervention has begun. Follow-up data collections may be interim data collections (conducted partway through the intervention) or post-tests (conducted after the intervention is over). In addition to the behaviors and intentions, demographic data need to be reported as we cannot link these data with the data reported for the reach performance measure. The specific items required for behaviors/intentions measures are shown in Exhibit G in the Appendix.

When reporting behaviors/intentions data, evaluators should first select from the menu under the *participant-level data* tab whether they are reporting baseline data or interim/post test data. If they are reporting interim/post test data, they will then be asked to report whether it is interim data (and how many months after the program began the data were collected) or post test data (and how many months after the program ended the data were collected). Evaluators will also need to indicate whether the data are for an intervention or control participant. For those using Option 1, there is a required field on the web data entry form labeled “Group Type.” Evaluators will need to mark the applicable radio button “Treatment” or “Control” for each participant. For those using Option 2, there is a variable on the spreadsheet named “*Group Type*” that takes the form “1” for treatment and “2” for control. Each participant will need to have one of these indicated. All of the behaviors/intentions data may be reported by uploading a spreadsheet containing the same variables that are on the website.

See **Exhibit G** for a complete list of the TPP Performance Measures.

## **V. EVALUATION PROGRESS REPORT for TPP TIER 1 A/B GRANTEES**

Range A/B grantees conducting their own evaluations are encouraged to document their evaluations and submit information on its progress in their continuation application. Data collected should demonstrate progress on achieving program outcomes and goals outside of the OAH performance measures. Grantees can include their evaluation updates within their work plan or as a separate, brief narrative.

Descriptions for the following can be included in the update:

- Methods for collecting data (e.g. pre/post surveys, focus groups)
- Incentives provided to students for participating in evaluation/program activities
- Output data (e.g. number of students served, dosage, frequency, size of group(s), etc.)
- Quality of services (e.g. student surveys of teacher/facilitator performance, additional observations outside of OAH requirements, etc.)
- Recommendations for adaptations or other program changes for the future
- Conclusions

## **VI. EVALUATION PROGRESS REPORT for TPP TIER 1 C/D AND TIER 2 GRANTEES**

The evaluation progress report for TPP Tier 1 C/D and Tier 2 grantees should be completed only by grantees not participating in the Federal evaluation and must include:

- A. Sample Intake and Equivalence of the Study Groups on Baseline Measures
- B. Impact Analysis Plan

## A. Sample Intake and Equivalence of the Study Groups on Baseline Measures

All TPP Tier 1 C/D and Tier 2 grantees not participating in the federal evaluation need to provide information on two key components of their independent, grantee-level rigorous evaluation: sample intake and equivalence of the study groups on baseline measures. Monitoring these two aspects of your evaluation are important for understanding whether your implemented evaluation is maintaining the rigor of the original design. Documenting the sample intake process and reporting on sample equivalence using baseline measures will also be important to include in study reports for HHS and peer-reviewed journal articles. This information should be provided by your independent evaluator.

Examining sample intake throughout the study is important for two reasons: 1) assessing whether you are meeting your target sample size on which power calculations were based, and 2) assessing the likelihood that the final study sample might have rates of overall or differential attrition that exceed the HHS evidence standard threshold. For random assignment studies, if attrition rates exceed the threshold, establishing equivalence of the analytic sample on baseline measures is necessary for establishing that the design is internally valid.<sup>2</sup> Per HHS evidence standards, all quasi-experimental designs must establish that the analytic sample is equivalent on baseline measures. Understanding early levels of and reasons for attrition, and whether treatment and comparison groups differ on key characteristics measured at baseline provides some guidance for evaluators on targeting resources towards maximizing consent rates and response rates, either overall, by study condition, or by subgroups. We recommend that you examine attrition and equivalence of the samples on baseline measures before completing each data collection effort.

We recognize that sample enrollment and data collection may be limited or incomplete at this time. For this report, please provide the most recent information available by the time you submit the report.

For grantees that provided annual reporting data in November, 2011, please update your reporting with the most recent information available. Update your CONSORT diagram with additional baseline and/or follow-up data collected and reassess equivalence of the sample of youth with baseline data, as well as assess the equivalence of the sample with follow-up data.

Included below is a description of the items requested regarding sample intake and sample equivalence. **Exhibits H and I** include template and example flow charts, respectively, that can be used to report sample intake. **Exhibits J and K** include template and example spreadsheets, respectively, that can be used to report baseline equivalence.

### **Sample intake documentation**

The following pieces of information are needed to document the sample intake process and size of the current sample:

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<sup>2</sup> See the [HHS evidence review standards](#) for more information about the tolerable levels of overall and differential attrition and requirements for establishing baseline equivalence.

***For clustered random assignment designs*** (for example, clinics, community-based organizations, teachers, or schools were randomly assigned):

- A paragraph describing: the definition of clusters eligibility for the evaluation, the number of clusters considered/recruited, the outcome of that recruitment effort, and whether and how any clusters were prioritized for inclusion in the evaluation sample. This paragraph will provide a clear summary of the recruitment process for clusters, the outcome of that process, and an indicator of the population to which the evaluation results may be generalizable.
- The number of clusters randomly assigned to each condition (i.e., treatment and comparison).
- The number of clusters still participating after random assignment (i.e. that did not drop out) at each time point, by study condition, and the reason(s) for nonparticipation of clusters.
- Whether subclusters (for example, the youth) are also randomly assigned and the timing of that random assignment. If subclusters (youth) are not randomly assigned, please describe in a paragraph how subclusters (youth) are assigned to the cluster and the timing of that assignment with respect to the timing of cluster random assignment.
- And the items below *for those clusters still participating*<sup>3</sup>

***For all designs:***

- A paragraph describing what makes a youth eligible for the evaluation; the number of youth screened and determined to be eligible and the counts and reasons for those screened out; and the process for selecting the pool to be evaluated among those eligible.
- The number of youth eligible to receive the program.
- The number of youth consenting for the evaluation (by condition, if post-random assignment).
  - If program consent was separate from evaluation consent, please include the sample sizes for those youth with evaluation consent who did not consent to the program.
- The number of youth randomly assigned to each condition.
- The number of youth with baseline data, by condition.
- The number of youth with follow-up data, by condition.
- The start and end dates for each data collection point, by condition.
- The start date and end dates for the program (and comparison condition, if applicable).

You should provide this information pooled across cohorts, even if some cohorts are incomplete.<sup>4</sup> The documentation should include the order in which the following activities

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<sup>3</sup> Under the HHS evidence standards, attrition at the sub-cluster level is assessed after accounting for cluster-level attrition. So the starting point for the student level information should be the students recruited in the clusters that are still participating.

<sup>4</sup> We are requesting information pooled across cohorts because it will provide the necessary information used in the HHS evidence standards attrition calculation. However, you may also want to calculate this for each



occurred and whether those activities are completed or ongoing: eligibility screening, consent, random assignment, and baseline data collection. It should also provide the reason for sample loss, if not obvious from the items provided above (for example, non-consent). Template flow charts are provided in **Exhibit H**. You should customize the flow charts to reflect your research design. For cluster-level assignment, please provide the information requested in *both* charts.

Importantly, when completing the CONSORT diagrams, it is expected that the sample sizes for each box are complete and allow a reader to follow the flow of study participants from the time of random assignment through each data collection time point (baseline, first follow-up, second follow-up, etc.). Three example CONSORT diagrams have been included in **Exhibit I** (two for a cluster RCT design – the first for clusters and the second for the youth in that study -- and one for an individual RCT design) to illustrate the types of information that would be helpful for the review. Please note that in both of these diagrams, the number of clusters/individuals described at each data collection event can be mapped directly back to the number of clusters/individuals randomly assigned to condition.

While HHS evidence standards do not include an attrition assessment for quasi-experimental designs, understanding sample loss by condition is valuable for determining whether there could have been intervention-induced loss, and also for assessing the representativeness of your final sample. Therefore, those with quasi-experimental designs should also provide all data requested to assess sample flow.

### **Baseline equivalence documentation**

All grantees, regardless of research design, should provide baseline characteristics for 1) the sample of youth with baseline data and 2) the sample of youth with follow-up data. For instance, if you have completed baseline and first follow-up data collection for your first cohort, please provide two baseline equivalence tables. The first table should assess baseline equivalence for the entire sample of youth with baseline data. The second table should assess baseline equivalence for the sample for which you have first follow-up data.

For randomized controlled trials, assessing baseline equivalence is important for assessing whether random assignment resulted in equivalent groups. For quasi-experimental design studies, this is useful for understanding whether your targeted groups are similar, as had been hypothesized. Later, when the evaluation is completed, HHS evidence standards require that randomized controlled trials with high attrition and all quasi-experimental designs establish that their analytic samples are equivalent on baseline characteristics. While your evaluation sample may not be final yet, if there are observed differences on key baseline characteristics between the groups at this time, data collection efforts could be adjusted to either survey enough youth to get below the (overall or differential) attrition threshold or target students with particular characteristics to bring the sample into equivalence.

The HHS evidence review assesses equivalence on three key demographic characteristics (age or grade level if age is not available, gender, and race/ethnicity) and, if the sample is age 14 (eighth grade) or older at baseline, on at least one behavioral outcome measure (for example, rates of

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cohort to identify the populations to focus on tracking to ultimately improve attrition rates or balance baseline equivalence.

sexual initiation). Therefore, *again after pooling across all cohorts*, please provide sample sizes<sup>5</sup>, unadjusted means, and standard deviations for the demographic measures and the OAH behavioral performance measures you collected at baseline for 1) the sample with baseline data and 2) the sample with outcome data. If you have outcome data for two follow-ups, please include an equivalence table for each follow-up, using the respective sample with outcome data in each follow-up.

In **Exhibit J**, we present an excel worksheet you can use to assess baseline equivalence. In **Exhibit K** we present a completed example. The excel workbook containing both of those tabs (template and example) is available on the [Eval TA SharePoint website](#). The excel worksheet contains equations for calculating t- and chi-square statistics and p-values for the group differences on each of the baseline characteristics. If you perform alternate tests of statistical significance (such as adjusting standard errors for random assignment of clusters), please include those as well with a note about the test performed.

When using the excel spreadsheet, enter data in the yellow highlighted areas only. It is unnecessary to enter any data into the grey cells (there will be a large “X” in cells that do not require data entry). Sometimes you will enter only means (for binary variables), sometimes you will enter means and standard deviations (for continuous variables), and sometimes you will enter counts (for race). When entering means for binary variables, please make sure they are entered with decimals (i.e. 0.05, not 5) or statistical tests will not be calculated correctly. The table shell has separate constructs for race and ethnicity to align with the performance measures data request and minimize the data processing burden of this request. However, if you wish to present a combined race-ethnicity measure and/or collapse racial-ethnic categories that have small sample sizes as you would in your analysis, you should feel free to do that. You should then re-label the categories in the excel file to line up with your analyses.

NOTE: we want to assess equivalence between the treatment and control groups for the full analytic sample, not just the subset with responses to a particular question. Therefore, for all behavioral measures except ever had sexual intercourse (which is already a full sample measure), please impute responses for respondents who skipped out of those questions. For instance, respondents who reported never having sexual intercourse should be imputed as never having been pregnant or gotten someone pregnant, never having had sex in the past three months, never having had sex in past three months without a condom, and never having had sex in past three months with an effective method of contraception. They should also be imputed to zero in the four corresponding number of times measures so that they are represented in the means as never having had sex, etc. The corresponding sample sizes for all of the behavioral measures should be the full analytic sample, minus any item non-response not due to skip patterns.

See **Exhibits H and I** for Template and Example Flow Charts for presenting sample intake data.

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<sup>5</sup> Please clearly indicate the sample sizes for these measures. It is possible you will have collected more baseline data than is prepared for analysis, resulting in a discrepancy between the sample size reported in the sample flow section and the baseline equivalence assessment. We need to be clear on the sample size of the baseline measures reported in the table.

See **Exhibit J and K** for Template and Example Excel Worksheets for presenting baseline equivalence data.

## **B. Impact Analysis Plan**

All TPP Tier 1 C/D and Tier 2 grantees not participating in the federal evaluation need to provide an impact analysis plan. The impact analysis plan should be structured around tests of program effectiveness on behavioral outcomes relevant to the Evidence Review. In addition, the analysis plan will include descriptions of the intervention, the comparison condition, and the study design, and will provide details on how the primary and secondary research questions will be answered.

Analysis plans should differentiate between primary and secondary research questions, multiple comparison and cluster adjustments should be applied appropriately, and findings should be reported as differences in means or proportions at a single point in time (for example, six months post-intervention). All of these decisions pertain to this analysis plan only; grantees and their evaluators may choose to analyze impacts on behavioral outcomes in different ways (for example, to use growth curve models) and/or to address different research questions for other publications, such as journal articles. At the end of the plan, you are asked to list all of additional research questions you will address. Please address each item in the analysis plan template; if an item is not relevant to your design, explain why. A well constructed, well written analysis plan will go a long way towards your end of grant reporting requirement, as well as other publications such as journal articles.

All grantee analysis plans should include:

1. Research questions that address program effectiveness on behavioral outcomes
  - a. Primary research questions
  - b. Secondary research questions
2. Description of the intervention and counterfactual condition
  - a. Intervention condition (intended program components, intended program dosage, intended program content, intended program delivery)
  - b. Counterfactual condition (intended program components, intended program dosage, intended program content, intended program delivery)
3. Study design
  - a. Sample formation (eligibility criteria for target population, purposeful sampling)
  - b. Research group formation (for quasi-experimental design)
  - c. Random assignment process (for random assignment design)
  - d. Consent process
  - e. Data collection
  - f. Outcome measures
4. Analysis
  - a. Data cleaning

- b. Assessment of baseline equivalence
  - c. Analytic approach for primary research questions (analytic sample, model specification, covariates, missing data approach, sample weights, adjustments for multiple comparisons, sensitivity analyses)
  - d. Analytic approach for secondary research questions
- 5. Plans for presentation of results
  - a. Provide empty table shells of how findings will be presented to demonstrate sample flow, non-response analysis, baseline equivalence of analysis sample, and program impacts.
- 6. Additional planned analyses

See **Exhibit L** for the analysis plan template and supporting tables.

## **VII. BUDGET INFORMATION**

This section of the non-competing continuation grant application includes the proposed budget for the upcoming budget period and a narrative budget justification. The budget request should support and align with the proposed work plan. Items required to complete activities in the work plan should be budgeted.

In addition to the Federal funds requested, the budget information must include other Federal and non-Federal funds used to carry out the objectives included in the work plan.

### **A. The SF-424A Budget Information**

The non-competing continuation grant application must include an SF-424A Budget Information Non-Construction Program Form. Instructions for completing the SF-424A are found in the non-competing continuation application kit on [www.grantsolutions.gov](http://www.grantsolutions.gov). The guidance below provides supplemental information to these instructions.

#### **1. SF 424A, Section A: Budget Summary**

Columns – Federal (c.) and Non-Federal (d) must be completed by all grantees to report the estimated amount of funds for each category which will remain unobligated at the end of the current year two grant funding period. In column (e.) enter total Federal amount for year 3. If applicable, in column (f.) enter the total Non-Federal in-kind or required matching contribution amount for year 3.

#### **2. SF 424A, Section B: Budget Categories**

This section is a summary of all budget calculations and information for the budget period. Use Column 1 for the basic OAH program budget. The Columns could be used as follows: Column 1-Federal and Column 5-Total Federal.

The budget categories/object class categories on the 424A are to reflect the grantee's total proposed Federal costs for: Personnel, Fringe Benefits, Travel, Equipment, Supplies, Contractual, Other, and Indirect Costs. More specificity about the costs in each of these object class categories should be presented in the grantee's detailed budget and budget narrative justification.

### **3. SF 424A, Section C: Non-Federal/Matching Resources**

The grantee should include realistic revenue projections that reflect actual sources of income for the project. Program income includes, but is not limited to, income from fees for services performed, the use or rental of real or personal property acquired under Federally-funded projects, the sale of commodities or items fabricated under an award, and license fees and royalties on patents and copyrights.

### **4. SF424A, Section F: Other Budget Information**

Indirect cost rates budgeted for the grantee and sub-recipients should be in accordance with the indirect cost agreement allowing such costs. The grantee must have a current and approved indirect cost rate agreement or an accepted cost allocation plan with DHHS or another Federal agency in order to claim reimbursement for indirect costs.

## **B. Detailed Budget and Budget Justification**

Provide budget information that includes itemized detail by object class category. If there are budget items for which costs are shared with other federal or non-federal programs, the basis for the allocation of costs should be explained. A budget and budget narrative justification should be submitted for the upcoming year of the project that is detailed, reasonable, adequate, cost efficient, and that is derived from the proposed work plan. Sufficient detail should be provided so that the reviewer is able to determine the adequacy and appropriateness of budgeted items related to the proposed activities. From the detailed budget and the budget narrative justification, the reviewer should be able to assess how the budget relates directly to the goals and objectives in the proposed work plan.

The following level of detail should be provided:

### **1. Personnel and Fringe Benefits**

- a. Identify each staff position
- b. Provide the names of each staff person identified for each position and the annual salary, number of months and percentage of time allotted to the project. If a key position is vacant, include the anticipated hiring date.
- c. Provide a listing of all remaining filled and vacant positions, percentage of time allocated to the project, number of months, and projected salaries.
- d. Itemize the components that comprise the fringe benefits rate (e.g., health insurance, FICA, life insurance, retirement plan, etc.).

## **2. Travel**

Identify the purposes of travel to include locations, names of conference/training if available. Costs can be aggregated by category/purpose, numbers of staff and trips (e.g., project director meetings, site evaluations, training). Costs for each category/purpose should be provided. Remember that you are required to budget travel for staff to attend the annual OAH grantee conference each year. The specific travel requirements are included in the original FOA.

## **3. Equipment**

List only those equipment items costing \$5,000 or more per unit.

## **4. Supplies**

Categorize supplies according to type, such as office supplies, training materials, etc. List items under supplies with cost less than \$5,000 per unit.

## **5. Contractual**

List all sub-recipients/delegate agencies and/or contract providers and the amount of OAH funds and non-OAH resources allocated/contributed for each. Provide an itemized budget with a detailed justification for the costs associated with each contract. From the itemized budget, the reviewer should be able to assess how the total amount requested for the contract was determined.

## **6. Other**

Itemize all costs in this category and explain each in sufficient detail to enable determinations for whether each cost is allowable. In most cases, consultant costs for technical assistance, legal fees, rent, utilities, insurance, printing, dues, subscriptions, and audit related costs would fall under this category.

## **7. Indirect Costs**

Grantees must have a current and approved indirect cost rate agreement or an accepted cost allocation plan with HHS or other Federal agency in order to claim indirect reimbursement costs. Provide an explanation of the calculation of indirect costs that includes the rate, the base, how the base is calculated, and the total amount. Identify the amount of indirect cost charged to the Federal share of the budget.

## **VIII. APPENDICES**

Supporting documents that add value or clarity to the information presented in the progress report or work plan should be included in the appendices. Materials included in the appendices should present information clearly and succinctly. Extensive appendices are not required.

## **PART FOUR: EXHIBIT INFORMATION AND SAMPLE FORMATS**

EXHIBIT A. EXAMPLE PROGRESS REPORT TEMPLATE

EXHIBIT B. EXAMPLE PROGRESS REPORT

EXHIBIT C. EXAMPLE WORK PLAN TEMPLATE #1

EXHIBIT D: EXAMPLE WORK PLAN TEMPLATE #2

EXHIBIT E: EXAMPLE WORK PLAN

EXHIBIT F. CONTINUATION APPLICATION CHECKLIST FOR TPP GRANTEES

EXHIBIT G. TPP PERFORMANCE MEASURES

EXHIBIT H. TEMPLATE FLOW CHARTS FOR SAMPLE INTAKE DATA

EXHIBIT I: EXAMPLE FLOW CHARTS FOR SAMPLE INTAKE DATA

EXHIBIT J: TEMPLATE EXCEL WORKSHEET FOR BASELINE EQUIVALENCE DATA

EXHIBIT K. EXAMPLE EXCEL WORKSHEET FOR BASELINE EQUIVALENCE DATA

EXHIBIT L: IMPACT ANALYSIS TEMPLATE & SUPPORTING TABLES

**EXHIBIT A – Example Six-Month Progress Report Template****Name of Grantee****Grant #:****September 1, 2012 – February 28, 2013****Goal:**

<b>Objective:</b>	<b>In Progress</b>  <b>Met</b>  <b>Unmet</b>	<b>Provide a brief description of the accomplishments, barriers encountered, populations served, activities undertaken and the collaborative partners involved in working toward the objective. Document any outcomes that are a result of your grant-funded activities. Provide a justification for any objectives that are not currently either in progress or met along with a description for how you are planning to proceed on any unmet objectives.</b>
<b>Activity:</b>	<b>In Progress</b>  <b>Met</b>  <b>Unmet</b>	<b>Describe the activities that have taken place to date and any barriers encountered. Document any outcomes that are a result of your grant-funded activities. Provide a justification for any redirection of activities (i.e. unmet, revised).</b>
<b>Activity:</b>	<b>In Progress</b>  <b>Met</b>  <b>Unmet</b>	<b>Describe the activities that have taken place to date and any barriers encountered. Document any outcomes that are a result of your grant-funded activities. Provide a justification for any redirection of activities (i.e. unmet, revised).</b>
<b>Activity:</b>	<b>In Progress</b>  <b>Met</b>  <b>Unmet</b>	<b>Describe the activities that have taken place to date and any barriers encountered. Document any outcomes that are a result of your grant-funded activities. Provide a justification for any redirection of activities (i.e. unmet, revised).</b>



## **EXHIBIT A – Six-Month Progress Report – p. 2**

### **Additional Narrative**

Report on any other significant project activities, accomplishments, setbacks or modifications (e.g. change in key staff, change in scope) that have occurred in the current budget period and were not part of the program work plan. These should include legislative and/or judicial actions impacting the program, as well as agency events.

### **Trainings**

Please provide feedback on the OAH provided trainings and technical assistance provided, including TA webinars, tip sheets, evaluation webinars, and evaluation briefs. Please provide specific comments on what you as a grantee have found useful and what areas you would like to see improved upon.

**EXHIBIT B: Example Six-Month Progress Report (Partial)*****Grantee X; Grant #:xxxxx*****September 1, 2012 – February 28, 2013****Goal:** Replicate xxx evidence-based program in 60 sites across xxx County.

<b>Objective:</b> By August 31, 2012 train all facilitators in the xxx evidence-based program model.	<b>In Progress</b>	By the end of the first grant year, we will have trained all 60 facilitators in the xxx evidence-based program model. To date, we have accomplished 75% of the activities under this objective. We searched for organizations that were certified to conduct training on the evidence-based program, had a conversation with each organization about the content and cost of their training, selected and entered into an agreement with xxx organization to conduct our trainings, and have conducted two of the four facilitator trainings. We're offering the same training four times to provide options in the location and timing of the training and to limit each training to no more than 15 participants. The remaining two trainings will be completed in May.
<b>Activity:</b> Identify and secure a trainer to conduct training on xxx evidence-based program.	<b>Met</b>	We identified three organizations that were certified to conduct trainings in xxx evidence-based program. We contacted each organization to learn more about the content and cost of their training. Each organization offered a three-day training, but one organization also included 20 hours of follow-up technical assistance in their training plan. The cost estimates from the three organizations were similar. We decided that having the 20 additional hours of technical assistance from the trainer would be beneficial since this is a new program for all of our facilitators, therefore we selected xxx organization. We signed a contract with xxx organization to conduct four identical three-day trainings for our facilitators and to provide 20 hours of follow-up technical assistance. It was agreed that our organization would take care of the logistics and registration for each training.
<b>Activity:</b> Conduct four, 3-day trainings in the xxx evidence-based program for program facilitators.	<b>Partially Met</b>	Training dates and locations for four 3-day trainings were secured: March 22-24 (xxx location in Kansas City); April 14-16 (xxx location in Baltimore, MD); May 2-4 (xxx location in St. Louis); and May 20-22 (xxx location in Atlanta)  Trainings were advertised to the 60 facilitators who are implementing the xxx evidence-based program. Each training includes an overview of the program model, core components, and teaching philosophy; a detailed review of the activities included in the program; time for each participant to practice delivering the program activities; review of the fidelity monitoring tools; discussion about allowable adaptations; and review of the available evaluation tools (see Appendix A – Training Agenda). Training participants completed an evaluation form after the training. Results have been analyzed for the first two trainings and indicate that facilitators are confident in their ability to implement the program with fidelity as a result of the training.

### EXHIBIT C – Example Work plan Template

September 1, 2013 – August 31, 2014

Grantee Name \_\_\_\_\_

Funds Requested \_\_\_\_\_

<i>Goal I:</i>		
<i>Objective 1:</i>		
<i>Rationale</i> for Objective 1:		
Measures of Accomplishment for Objective 1: a.  b.  c.		
<i>Activities</i> in support of Objective 1:  a.  b.  c.	Person/agency responsible for <i>Accomplishing Activities</i> .  a.  b.  c.	<i>Activity Timeline</i> .  a.  b.  c.

# EXHIBIT D – Example Work plan Template

September 1, 2013 – August 31, 2014

Grantee Name \_\_\_\_\_

Funds Requested \_\_\_\_\_

Goal I: Goal Statement															
Objectives	Activities	Timeline												Measures of Accomplishment	Person Responsible
		S	O	N	D	J	F	M	A	M	J	J	A		
Objective 1:    Objective Rationale:	Activity 1:														
	Activity 2:														
	Activity 3:														
	Activity 4:														
	Activity 5:														
Objective 2:  Objective Rationale:	Activity 1:														
	Activity 2:														
	Activity 3:														

## Work plan Instructions

- 1) **Name:** Name of the grantee organization.
- 2) **Funds Requested:** Funds requested for project period.
- 3) **Goal 1:** A broad statement of program purpose which describes the expected long-term effects of a program. Goals should address the program's effect in reducing a health problem and identify the target population to be affected. Although only Goal I is shown as an example in the suggested work plan format, you should include all programmatic goals in your work plan.
- 4) **Objective 1:** A statement describing the results to be achieved and the manner in which these results will be achieved. Objectives should be **SMART**, that is, **S**pecific, **M**easurable, **A**chievable, **R**ealistic, and **T**ime-phased. **Specific** objectives include *who* will be targeted and *what* will be accomplished; **measurable** objectives include *how much* change is expected specifically enough that achievement of the objective can be measured through counting or through documenting change or completion; **achievable** objectives can be realistically accomplished given existing resources and constraints; **realistic** objectives address the scope of the problem and reasonable programmatic steps; and **time-phased** objectives provide a time line indicating when the objective will be measured or a time by which the objective will be met. Although we only include one-two objectives in the example work plan template, you should list all objectives that support each goal in your work plan.
- 5) **Rationale for the Objective:** why you think the objective will contribute to accomplishing the goal. The objective should relate to the goal and should link to outcomes on the logic model leading to the desired outcomes. In addition, you may provide context that shows why this objective is necessary given your program's resources or constraints.
- 6) **Activities** - describe anticipated events that will take place as part of your program in support of the objective. Although we only include a few activities in the example work plan template for each objective, you should list all activities for each objective.
- 7) **Timeline for Activities** – identify when the activity will be implemented.
- 8) **Measurement of Accomplishment** – these are the quantifiable criteria that describe how you know if you succeeded in accomplishing an objective. Measures might include target numbers or they might include quantifiable changes or completion of an activity.
- 9) **Person Responsible** - who is most responsible for ensuring that each activity is accomplished.

**EXHIBIT E – Example Work plan**  
September 1, 2013 – August 31, 2014

<b>Goal I: Replicate xxx evidence-based program in 60 sites across xxx County.</b>															
<b>Objectives</b>	<b>Activities</b>	<b>Timeline</b>												<b>Measures of Accomplishment</b>	<b>Person Responsible</b>
		<b>S</b>	<b>O</b>	<b>N</b>	<b>D</b>	<b>J</b>	<b>F</b>	<b>M</b>	<b>A</b>	<b>M</b>	<b>J</b>	<b>J</b>	<b>A</b>		
<u><b>Objective 1:</b></u> By August 31, 2012 train all facilitators in the xxx evidence-based program model.  <u><b>Objective Rationale:</b></u> All facilitators need to be trained in the evidence-based program to replicate the program with fidelity.	<u><b>Activity 1:</b></u> Research organizations available to provide training on the evidence-based program		X											Potential training organizations identified	Project Director
	<u><b>Activity 2:</b></u> Secure contract with organization selected to conduct training			X										Written contract in place with organization	Project Director
	<u><b>Activity 3:</b></u> Confirm training dates and locations for four 3-day trainings				X	X								Training dates and locations	Training Coordinator
	<u><b>Activity 4:</b></u> Collect registration information from 60 facilitators						X							Completed registration forms from 60 facilitators	Training Coordinator
	<b>Activity 5:</b> Conduct four 3-day trainings for facilitators							X	X	X				Training agendas, sign-in sheets, evaluation forms	Training Coordinator & Contractor

## EXHIBIT F: CONTINUATION APPLICATION CHECKLIST FOR TPP GRANTEES

### Instructions:

The content for this checklist is based on information noted in the Funding Opportunity Announcement (FOA) and is not meant to be exhaustive of everything that a grantee will want to include in its progress report, work plan, and budget. A grantee's progress report, work plan, and budget should describe the progress and plans for the grantee's overall program and may include objectives and activities in addition to those outlined in the checklist below.

### PROGRESS REPORT CHECKLIST FOR TPP GRANTEES

- ☐ Thorough narrative description on the status (met, ongoing, or unmet) of each objective and activity in the current year's work plan
  - Narrative description of work done during the reporting period toward accomplishing the planned activities
  - Description of any barriers encountered and how the barriers have been addressed during the reporting period
  - If applicable describe why any goals or objectives were not met and the assistance needed to resolve the situation
- ☐ Status of program implementation during the reporting period
  - Description of efforts to monitor fidelity of the program at all sites during the reporting period
  - Description of the number of sessions completed and number of youth served
  - Description of recruitment of program participants with discussion of successes, challenges/barriers; and how these challenges/barriers were addressed.
  - Description of retention efforts of program participants with discussion of successes, challenges and barriers; and how these challenges/barriers were addressed.
  - Activities to ensure all materials are medically accurate
  - Description of activities to market the program
  - Description of activities to build, enhance, and retain partnerships to support the program
  - Description of training and professional development opportunities for partners and/or facilitators
  - Description of dissemination efforts about the program through presentations or publications
  - Documentation of the program model (*Tier 2 only*) – status of developing core components, logic model, curriculum manual, training manual, adaptation guidance
- ☐ Status of project management activities including:
  - Description of staff recruitment and retention efforts
  - Description of staff training and professional development
  - Description of activities implemented to monitor implementation partners and/or contractors
- ☐ Progress on evaluation activities, including participation in the Federal evaluation, if applicable

- Extent to which evaluation activities are consistent with approved evaluation plan (Tier 1 C/D & Tier 2 Grantees)
- ☐ Description of activities focused on program sustainability
- ☐ Report on any other significant project activities, accomplishments, setbacks or modifications that have occurred during the reporting period and were not part of the current work plan.
  - Request for any new adaptations or add on activities
  - Changes in key staff
  - Change in scope of the project

### **Year Four Work Plan**

- ☐ Majority of objectives SMART
- ☐ Activities align with objectives and are consistent with previous year work plans
- ☐ Timeline for activities is appropriate
- ☐ Includes project management activity details
  - Recruitment and retention of staff
  - Staff training and professional development
  - Activities aimed at monitoring implementation partners and/or contractors to assess progress in meeting goals and objectives
- ☐ Plans to implement the program with fidelity in all sites (implementation plans due prior to implementation)
- ☐ Plans to recruit and retain program participants
- ☐ Activities to ensure all materials are medically accurate
- ☐ Activities to monitor implementation with fidelity
- ☐ Plans to collect, report, and use performance measure data to make continuous program improvements
- ☐ Plans to market the program
- ☐ Plans to build, enhance and sustain partnerships to support the program
- ☐ Plans to provide training and professional development for partners and/or facilitators
- ☐ Plans to disseminate information about the program (presentations, publications, etc)
- ☐ Activities related to any approved add-on activities
- ☐ Plans to document the program model (***Tier 2 only***) – core components, logic model, curriculum manual, training manual, adaptation guidance
- ☐ Program evaluation plans
  - Evaluation activities aligned with approved evaluation plan (***Tier 1 C/D & Tier 2***)
- ☐ Activities related to participation in the Federal evaluation (***if applicable***)
- ☐ Activities focused on program sustainability



#### Year Four Budget

- ☐ Detailed budget narrative with cost breakdown for each line item
  - Cost breakdown provided for all contracts
  - Provide the names of conferences, trainings, speakers, and other relevant details, if available.
- ☐ Budget aligns with work plan
- ☐ Includes funds for 3 people to attend the annual conference
- ☐ Indirect cost rate agreement on file
- ☐ Plans for cost sharing (*not required*)

## EXHIBIT G: TPP PERFORMANCE MEASURES

### Measures for youth $\geq 7^{\text{th}}$ grade

Construct	Performance measure	Questionnaire items (asked of participants)	Denominator
<b>Demographics (Inform Reach and Behaviors and Intentions)</b>			
	Age	In what month and year were you born? or How old are you? (must also record date survey is administered for this question)	All youth
	Grade	What grade are you in? (If you are currently on vacation between grades, please indicate the grade you will be in when you go back to school). <ul style="list-style-type: none"> <li>• 6<sup>th</sup></li> <li>• 7<sup>th</sup></li> <li>• 8<sup>th</sup></li> <li>• 9<sup>th</sup></li> <li>• 10<sup>th</sup></li> <li>• 11<sup>th</sup></li> <li>• 12<sup>th</sup></li> <li>• Ungraded</li> <li>• College/Technical school</li> <li>• Not currently in school</li> </ul> [List may be altered for specific age group being served]	All youth
	Gender	Are you male or female?	All youth
	Ethnicity	Are you Hispanic or Latino? [Grantees will indicate from this list ‘unknown/not reported’]	All youth
	Race	What is your race?	All youth

Construct	Performance measure	Questionnaire items (asked of participants)	Denominator
		<ul style="list-style-type: none"> <li>American Indian or Alaska Native</li> <li>Asian</li> <li>Black/African American</li> <li>Native Hawaiian or Other Pacific Islander</li> <li>White</li> </ul> [Grantees will indicate from this list ‘more than one race’ and ‘unknown/unreported’]	
	Language at home	When you are at home with your family, what language or languages do you usually speak? <ul style="list-style-type: none"> <li>English</li> <li>Spanish</li> <li>Chinese language such as Mandarin or Cantonese</li> <li>Some other language</li> </ul>	All youth
	Special Populations	Grantee will report if they specifically target a special population: <ul style="list-style-type: none"> <li>Pregnant or parenting teens</li> <li>Youth in foster care</li> <li>Homeless youth</li> <li>Youth in the juvenile justice system</li> <li>Other</li> </ul>	All youth
<b>Behaviors and Intentions (reported only by Tier 1C/D, Tier 2, PREIS, and Tier 1 A/B grantees if in the Federal evaluation)</b>			
Any sex*	The % of grantees whose intervention group reports less sexual activity than the comparison group	The (next/first) questions are about sexual intercourse. By sexual intercourse we mean a male putting his penis into a female’s vagina.  Have you ever had sexual intercourse? (yes/no)	All youth
		Now please think about the past 3 months. In the past 3	All youth

Construct	Performance measure	Questionnaire items (asked of participants)	Denominator
		<p>months, have you had sexual intercourse, even once? (yes/no)</p> <p>(If yes) In the past 3 months, how many times have you had sexual intercourse? (# of times)</p>	
Pregnancy*	The % of grantees whose intervention group reports fewer pregnancies since baseline than the comparison group.	<p>To the best of your knowledge, have you ever been pregnant or gotten someone pregnant, even if no child was born? (Yes/no)</p> <p>(If yes) To the best of your knowledge, how many times have you been pregnant or gotten someone pregnant? (#)</p>	All youth
Condom use*	The % of grantees whose sexually active intervention group reports more condom use than the comparison group	<p>In the past 3 months have you had sexual intercourse without you or your partner using a condom? (yes/no)</p> <p>(If yes) In the past 3 months, how many <u>times</u> have you had sexual intercourse <u>without</u> using a condom? (# of times)</p>	Youth who have had sex in past 3 months
Contraceptive use*	The % of grantees whose sexually active intervention group reports more contraceptive use than the comparison group.	<p>In the past 3 months, have you had sexual intercourse with you or your partner using any of these methods of birth control?</p> <ul style="list-style-type: none"> <li>• Condoms</li> <li>• Birth control pills</li> <li>• The shot (Depo Provera),</li> <li>• The patch,</li> <li>• The ring (NuvaRing)</li> <li>• IUD (Mirena or Paragard)</li> <li>• Implant (Implanon)</li> </ul> <p>(yes/no)</p>	Youth who have had sex in past 3 months

Construct	Performance measure	Questionnaire items (asked of participants)	Denominator
		(If yes) In the past 3 months, how many <u>times</u> have you had sexual intercourse <u>without</u> using any of these methods of birth control? (# of times)	
Intention to have sex *	The % of grantees whose intervention group reports a lower intention level than the comparison group to have sex in the next year	Do you intend to have sexual intercourse in the next year, if you have the chance? -Yes, definitely -Yes, probably -No, probably not -No, definitely not	All youth
Intention to use a condom*	The % of grantees whose intervention group reports a higher intention level than the comparison group to use a condom.	If you were to have sexual intercourse in the next year, do you intend to use (or have your partner use) a condom? -Yes, definitely -Yes, probably -No, probably not -No, definitely not	All youth
Intention to use contraception*	The % of grantees whose intervention group reports a higher intention level than the comparison group to use a contraceptive method.	If you were to have sexual intercourse in the next year, do you intend to use (or have your partner use) any of these methods of birth control? <ul style="list-style-type: none"> <li>• Condoms</li> <li>• Birth control pills</li> <li>• The shot (Depo Provera),</li> <li>• The patch,</li> <li>• The ring (NuvaRing)</li> <li>• IUD (Mirena or Paragard)</li> <li>• Implant (Implanon)</li> </ul> -Yes, definitely -Yes, probably -No, probably not -No, definitely not	All youth

\* These measures are based on rates of change in the treatment group compared to rates of change in the comparison group on the behavior/intention. No tests of significance will be conducted. Local evaluators will upload the raw data for these measures into the reporting system, and the performance measure contractor will perform the calculations.

## Grantee-level measures

Construct	Performance measure	Questionnaire item (asked of grantees, except for soundness of evaluations measures)
<b>Reach</b>		
# of youth served	# of youth served, by characteristics (e.g., age, gender, race/ethnicity, special populations)	<ul style="list-style-type: none"> <li>How many youth (classified by demographic characteristics) participated in your program for at least one activity during the reporting period?</li> </ul>
# of parents and other clients served	# of parents and other clients served	<ul style="list-style-type: none"> <li>How many other types of clients (e.g., parents or guardians, other family members, etc.) participated in your program for at least one activity during the reporting period?</li> </ul>
<b>Partners</b>		
# of partners	# of organizations/schools partnering with program	<ul style="list-style-type: none"> <li>How many partners are you currently working with? <ul style="list-style-type: none"> <li># Formal (A <i>formal</i> partner is a partner with whom the grantee has an MOU, contract or other formal written agreement in place to provide service or other contribution relevant to the TPP program)</li> <li>#Informal (An <i>informal</i> partner is a partner with who the grantee does not have a formal written agreement in place)</li> </ul> </li> <li></li> </ul>
Retention of partners	% of grantees that retain at least 70% of active program partners for their intended duration	<ul style="list-style-type: none"> <li>How many of the <i>formal</i> partners: <ul style="list-style-type: none"> <li>are new for this reporting period?</li> <li>did you lose this reporting period?</li> </ul> </li> <li></li> </ul>
<b>Training</b>		
Training of facilitators	# of new facilitators/teachers trained # of facilitators who receive follow-up training	<ul style="list-style-type: none"> <li>During the reporting period, how many new intervention facilitators (including teachers) have you or one of your partners trained? Please include only training provided to new facilitators.</li> </ul>

Construct	Performance measure	Questionnaire item (asked of grantees, except for <i>soundness of evaluations measures</i> )
		<ul style="list-style-type: none"> <li>• In the reporting period, how many intervention facilitators (including teachers) have you or one of your partners given follow-up or additional training?</li> </ul>
<b>Dissemination</b>		
Manuscripts and presentations (Years 3-5).	# of published and/or submitted manuscripts and national, regional or state-level presentations by grantees	NA (calculated based on responses to the below questions)
Manuscripts published	# of manuscripts published in journals	<ul style="list-style-type: none"> <li>• How many manuscripts have been accepted for publication but not yet published or published in a peer-reviewed journal during the reporting period? Do not include manuscripts previously reported as published.</li> <li>• Please list the references for any published manuscripts published in reporting period.</li> </ul>
Manuscripts submitted for publication	# of manuscripts submitted for publication	<ul style="list-style-type: none"> <li>• How many manuscripts have been submitted to a peer-reviewed journal for publication in the reporting period? Do not include manuscripts previously reported as submitted or published.</li> </ul>
Presentations	# of national, regional, or state-level presentations	<ul style="list-style-type: none"> <li>• How many presentations were made at each of the following levels in the reporting period: <ul style="list-style-type: none"> <li>○ National ____</li> <li>○ Regional ____</li> <li>○ State ____</li> </ul> </li> <li>• Please list titles of all presentations and venue (e.g., conference or organization to which the presentation was made)</li> </ul>
Packaging of Tier 2 programs for replication	% of Tier 2 grantees that have completed development of pieces of program necessary to package it for replication (e.g.,	<ul style="list-style-type: none"> <li>• Please indicate which of the following have been completed and approved: <ul style="list-style-type: none"> <li>○ Logic model</li> </ul> </li> </ul>



Construct	Performance measure	Questionnaire item (asked of grantees, except for <i>soundness of evaluations measures</i> )
	logic model, fidelity monitoring tools, manual)	<ul style="list-style-type: none"> <li>○ Core components</li> <li>○ Fidelity monitoring tools</li> <li>○ Curriculum manual</li> <li>○ Facilitator manual</li> <li>○ Training materials</li> <li>○ Adaptation Guidance</li> </ul>
<b>Dosage</b>		
Dosage	<p>Median % of total intended program services received by youth and/or parents</p> <p>% of youth/parents who received at least 75% of the program</p>	<p>Items derived from participant attendance data<sup>6</sup></p> <ul style="list-style-type: none"> <li>• What is the mean and median % of program services received by youth (as a whole and subdivided by age and gender) in the reporting period?</li> <li>• What is the mean and median % of program services received by other participants (if applicable) in the reporting period?</li> <li>• What % of youth (as a whole and subdivided by age and gender) received at least 75% of the program in the reporting period?</li> <li>• What % of other participants received at least 75% of the program in the reporting period?</li> </ul>
<b>Fidelity*</b>		
Adherence to program-specified activities (based on facilitator self-	% activities completed, based on facilitator self-assessment	<p>Items derived from session based fidelity data<sup>7</sup>:</p> <ul style="list-style-type: none"> <li>• For what percentage of completed sessions is there a completed fidelity monitoring log from the</li> </ul>

<sup>6</sup> Grantees will provide attendance for each participant for each session either directly on the website or by uploading spreadsheets; complete instructions are provided in the TPP Performance Measures Website Manual.

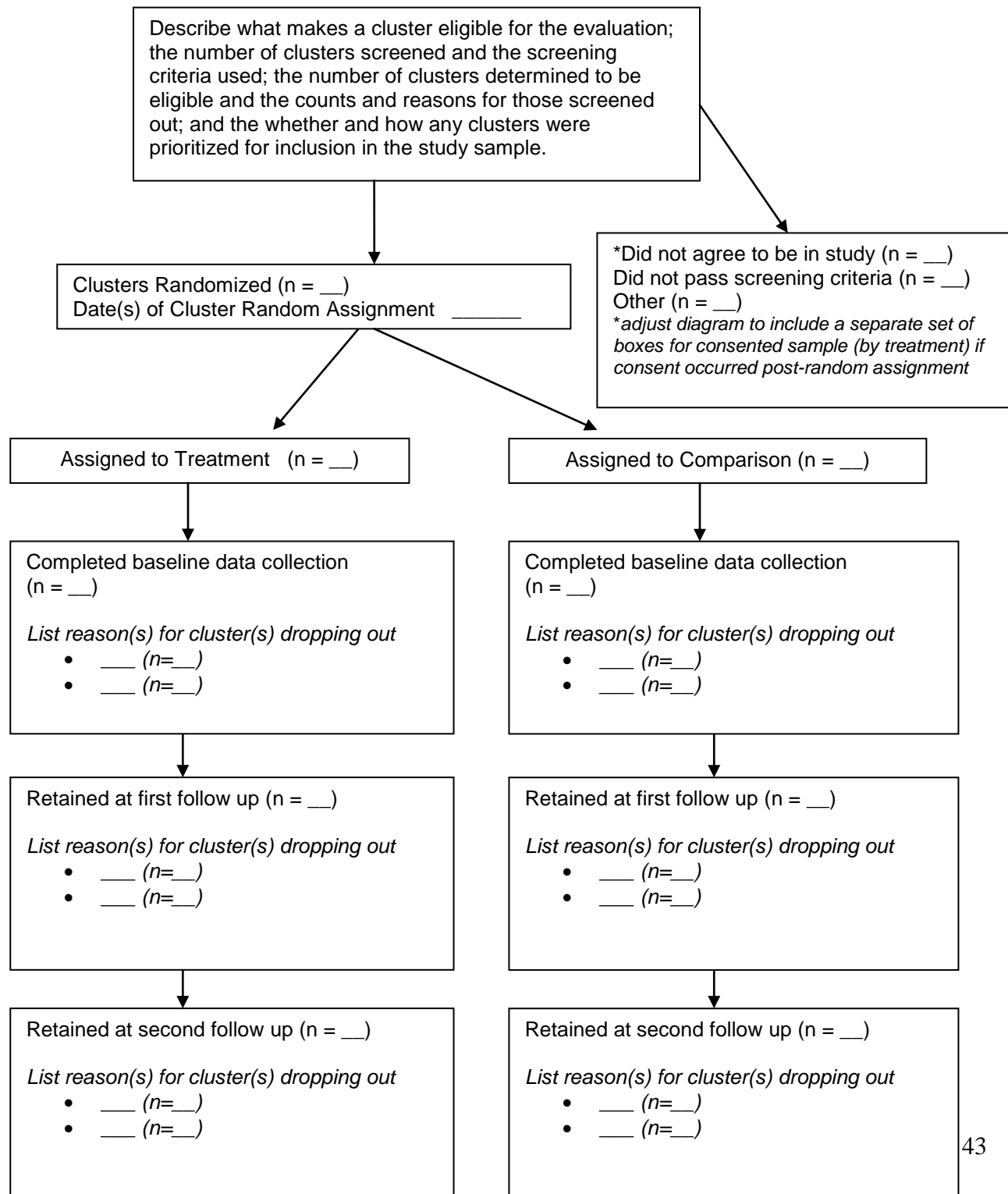
<sup>7</sup> Grantees will provide adherence data for each session either directly on the website or by uploading spreadsheets; complete instructions are provided in the TPP Performance Measures Website Manual.

Construct	Performance measure	Questionnaire item (asked of grantees, except for <i>soundness of evaluations measures</i> )
assessment)		<p>facilitator?</p> <ul style="list-style-type: none"> <li>• Using all of the facilitator completed fidelity monitoring logs (i.e., across all cohorts, sections, and sessions), what is the mean and median percentage of activities completed?</li> </ul>
Adherence to program-specified activities (based on observation)	% activities completed, based on observations	<p>Items derived from session based fidelity data<sup>2</sup>:</p> <ul style="list-style-type: none"> <li>• Across all sessions, what are the mean and median percentages of activities completed, by observation?</li> <li>• Across all sessions, what are the minimum and maximum percentages of activities completed, by observation?</li> </ul>
Quality of implementation (based on observation)	% of observed sessions that score 4 or higher on a 5-point scale of overall quality	<p>Items derived from session based fidelity data<sup>2</sup></p> <ul style="list-style-type: none"> <li>• Averaging over all scored questions on the TPP Program Observation Form, what percentage of sessions received ratings <math>\geq 4</math> for quality?</li> </ul>
Adherence to program-specified # of sessions	Median and mean % of sessions implemented, based on fidelity monitoring logs or other administrative records	<ul style="list-style-type: none"> <li>• Across cohorts, what are the mean and median percentages of total sessions implemented?</li> </ul>
System in place to ensure fidelity	% of grantees scoring $\geq 20$ on 22-point fidelity process scale	<ul style="list-style-type: none"> <li>• What is the score on the 11-item TPP Fidelity Process Report?</li> </ul>

## EXHIBIT H - TEMPLATE FLOW CHARTS FOR SAMPLE INTAKE DATA

### CONSORT Diagram for Clusters

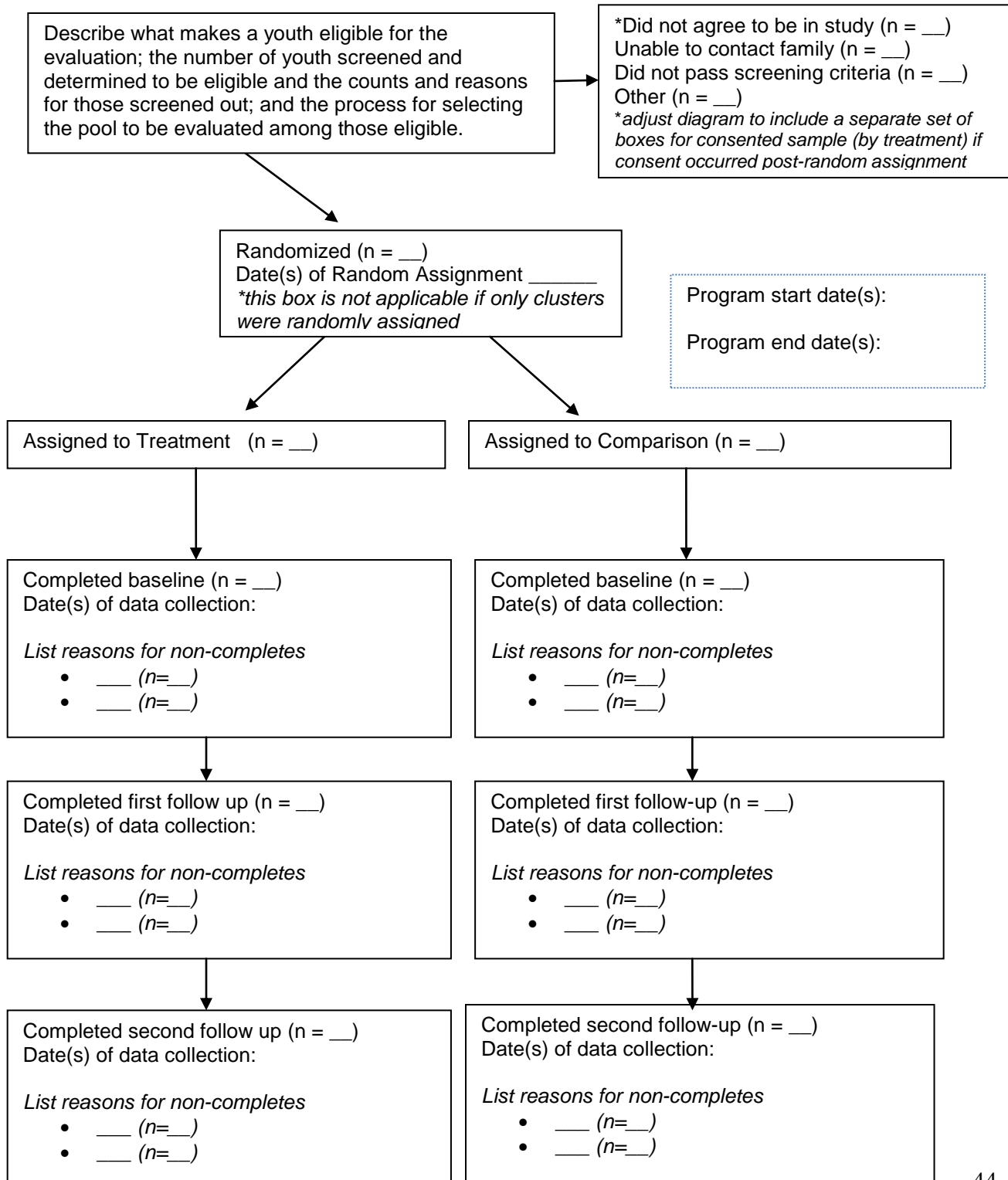
\*Please complete diagrams based on your pooled sample to date. Also complete diagram(s) for youth sample, using retained clusters as starting point.



## EXHIBIT H - TEMPLATE FLOW CHARTS FOR SAMPLE INTAKE DATA

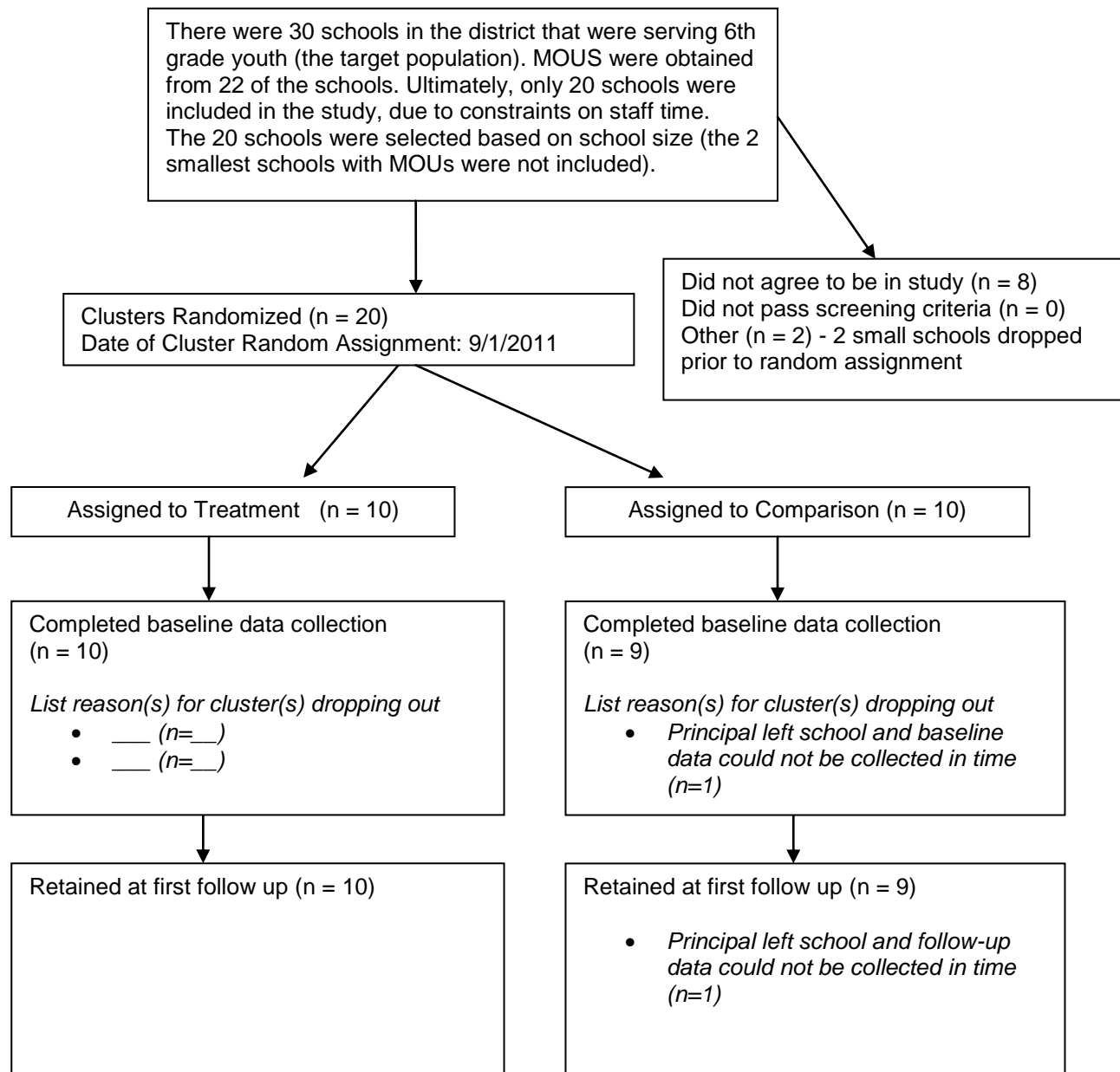
### CONSORT Diagram for Youth

\*Please complete diagram based on your pooled enrollment to date. Adjust order if not reflective of your processes.



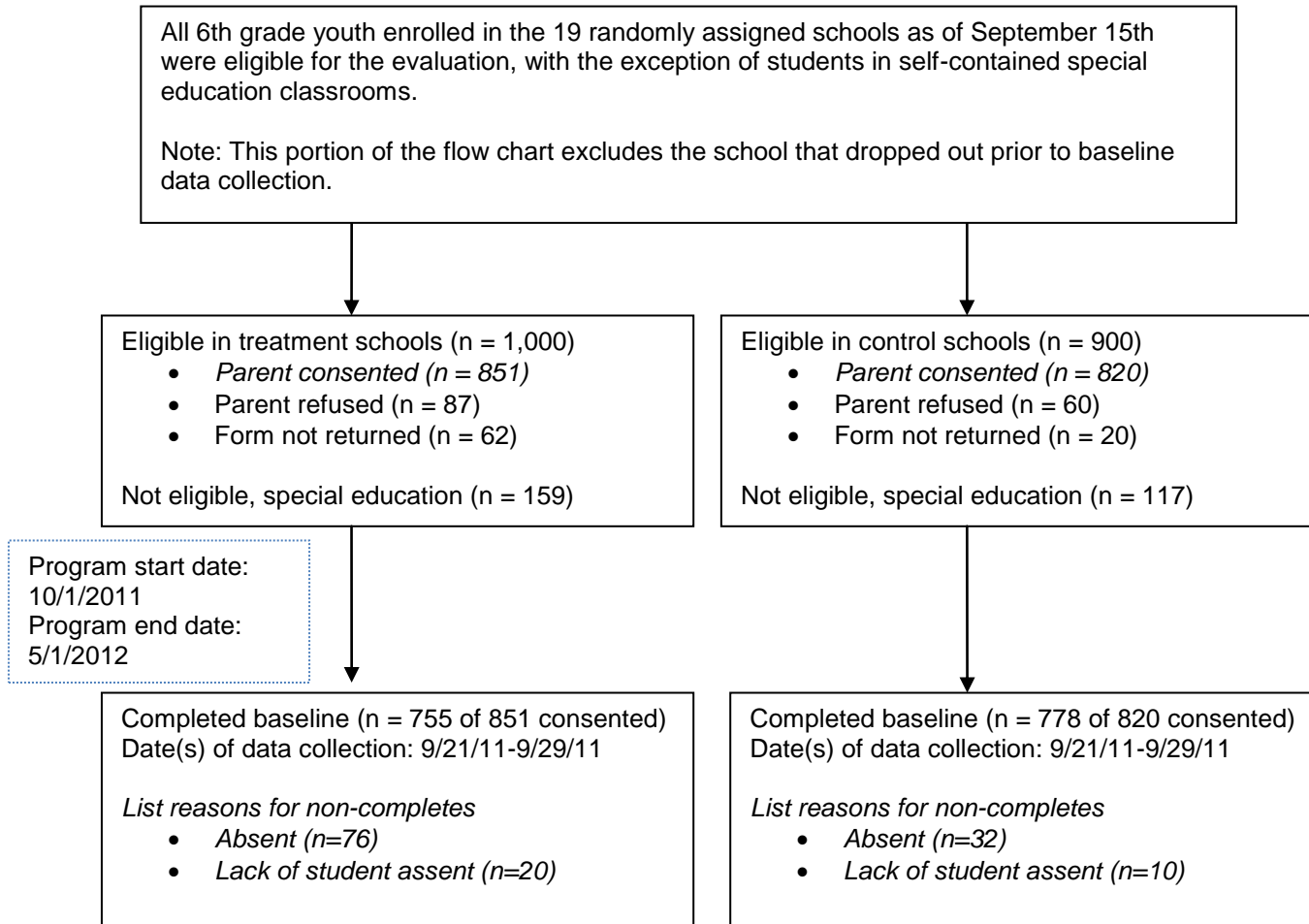
## EXHIBIT I - EXAMPLE FLOW CHARTS FOR SAMPLE INTAKE DATA

### CONSORT Diagram for Clusters in a Cluster Randomized Controlled Trial



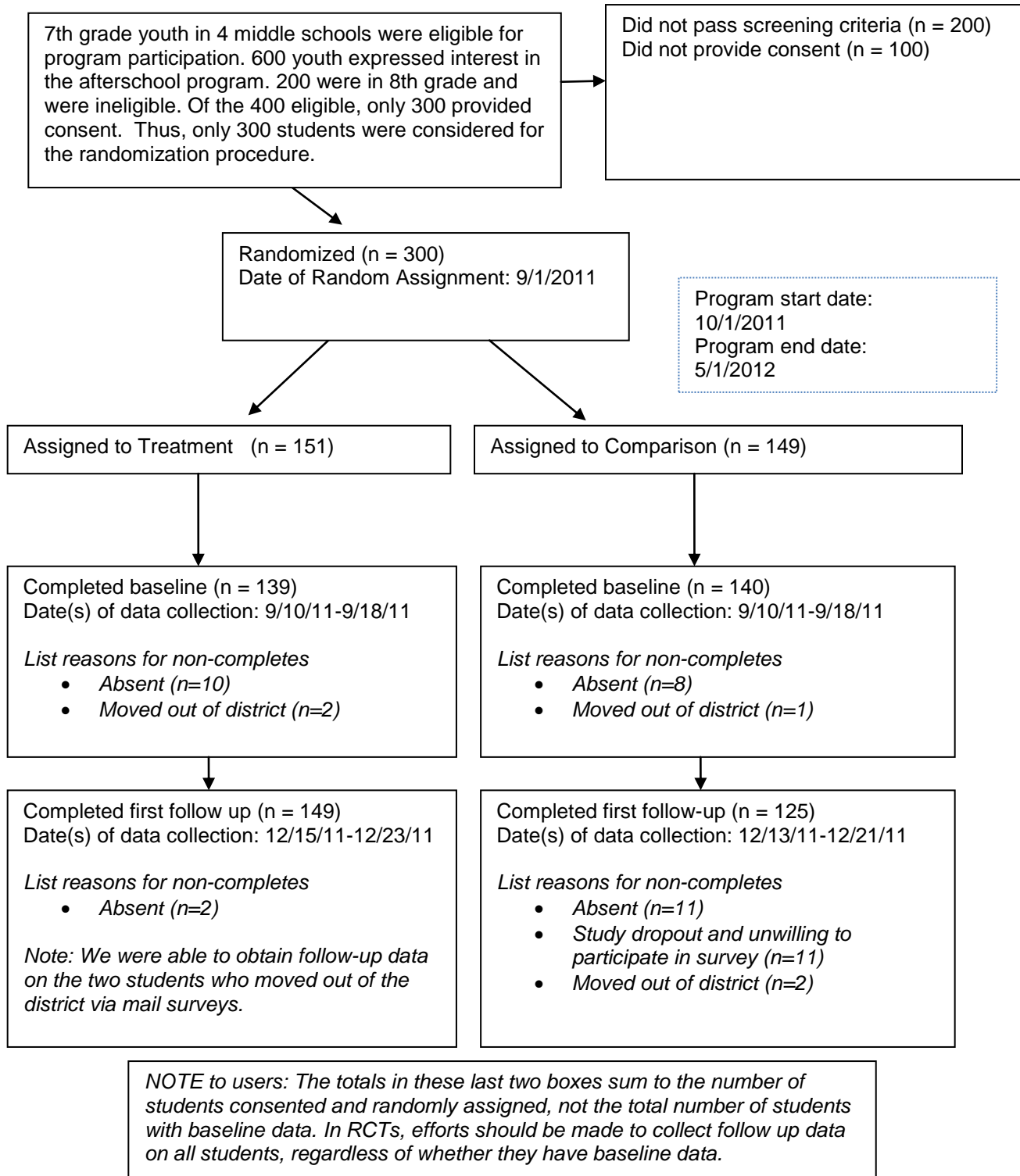
## EXHIBIT I - EXAMPLE FLOW CHARTS FOR SAMPLE INTAKE DATA

### CONSORT Diagram for the Youth in the Clustered Randomized Controlled Trial Presented on the Prior Page



## EXHIBIT I - EXAMPLE FLOW CHART FOR SAMPLE INTAKE

### CONSORT Diagram for Youth in a Design in Which Youth Were Randomly Assigned



## EXHIBIT J: TEMPLATE EXCEL WORKSHEET FOR BASELINE EQUIVALENCE DATA

Please indicate the sample for which you are assessing baseline equivalence:						<b>Sample with baseline data</b>					
						<b>Sample with first follow-up data</b>					
						<b>Sample with second follow-up data</b>					
		<u>Treatment Group</u>		<u>Comparison Group</u>		<u>Group differences</u>					
		Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	t-statistic (calculated by the worksheet)	df (calculated by the worksheet)	p-value (calculated by the worksheet)	p-value adjusted for clustering at level of random assignment, if applicable (calculated by the evaluator)
<b>Characteristics at BASELINE</b>											
<u>Demographic characteristics</u>											
Age (in years)											
Female (%)											
Hispanic (%)											
Race (% and counts) <sup>1</sup>				0							
American Indian or Alaska Native											
Asian											
Black											
Native Hawaiian or Other Pacific Islander											
White											
Two or more races											



## EXHIBIT J: TEMPLATE EXCEL WORKSHEET FOR BASELINE EQUIVALENCE DATA

	Treatment Group			Comparison Group			Group differences			
	Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	t-statistic (calculated by the worksheet)	df (calculated by the worksheet)	p-value (calculated by the worksheet)	p-value adjusted for clustering at level of random assignment, if applicable (calculated by the evaluator)
	Characteristics at BASELINE									
<u>OAH behavioral performance measures</u>										
Ever had sexual intercourse (%)										
Gotten someone pregnant or been pregnant (%) <sup>2</sup>										
Number of times (mean)										
Sexual intercourse in prior 3 months (%) <sup>2</sup>										
Number of times (mean)										
Sexual intercourse in prior 3 months without using condom (%) <sup>3</sup>										
Number of times (mean)										
Sexual intercourse in prior 3 months without using effective contraception (%) <sup>3</sup>										
Number of times (mean)										
Notes: Please enter data in the yellow highlighted cells only. Please convert all yes/no responses to yes = one and no = zero in your datafile. All binary outcomes should be entered as decimals in the spreadsheet (e.g. 45% should be entered as 0.45). For all "number of times measures," impute cases that skipped out because they had not had sex/gotten someone pregnant/etc to zero in the numerator so that the measure represents the full sample. <sup>1</sup> Please construct this variable, or a similar one, from the data. The percentages should sum to 100 percent. A chi-sq statistic is calculated for this variable (provided there are no rows with zero totals). <sup>2</sup> Impute those who have never had sex as zeroes in numerator. <sup>3</sup> Impute those who did not have ever or did not have sex in prior 3 months as zeroes in numerator.										

## EXHIBIT K: EXAMPLE EXCEL WORKSHEET FOR BASELINE EQUIVALENCE DATA

Please indicate the sample for which you are assessing baseline equivalence:				Sample with baseline data						
Treatment Group				Comparison Group			Group differences			
Characteristics at BASELINE	Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	t-statistic (calculated by the worksheet)	df (calculated by the worksheet)	p-value (calculated by the worksheet)	p-value adjusted for clustering at level of random assignment, if applicable (calculated by the evaluator)
<u>Demographic characteristics</u>										
Age (in years)	12.3	1.1	150	12.4	0.9	160	0.878	308	0.3804	
Female (%)	0.5		150	0.49		160	0.176	308	0.8604	
Hispanic (%)	0.2		150	0.1		160	2.475	308	0.0139	
Race (% and counts) <sup>1</sup>			150			160			0.0008	
American Indian or Alaska Native			20			30				
Asian			30			40				
Black			40			60				
White			60			29				
Two or more races			0			1				

Note: We did not have any students who indicated that they were Native Hawaiian, and deleted that row as per the instructions.

## EXHIBIT K: EXAMPLE EXCEL WORKSHEET FOR BASELINE EQUIVALENCE DATA

	Treatment Group			Comparison Group			Group differences			
	Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	Percentage or Unadjusted Mean	Standard Deviation (for continuous variables)	Sample Size	t-statistic (calculated by the worksheet)	df (calculated by the worksheet)	p-value (calculated by the worksheet)	p-value adjusted for clustering at level of random assignment, if applicable (calculated by the evaluator)
Characteristics at BASELINE										
<u>OAH behavioral performance measures</u>										
Ever had sexual intercourse (%)	0.03		150	0.02		160	0.565	308	0.5722	
Got someone pregnant or been pregnant (%) <sup>2</sup>	0.01		150	0.01		160	0.000	308	1.0000	
Number of times (mean)	0.02	0.01	150	0.00	0.005	160	21.356	308	0.0000	
Sexual intercourse in prior 3 months (%) <sup>2</sup>	0.2		150	0.15		160	1.160	308	0.2470	
Number of times (mean)	0.1	0.11	150	0.12	0.08	160	1.839	308	0.0669	
Sexual intercourse in prior 3 months without using condom (%) <sup>3</sup>	0.10		150	0.08		160	0.616	308	0.5384	
Number of times (mean)	0.1	0.22	150	0.09	0.08	160	0.538	308	0.5908	
Sexual intercourse in prior 3 months without using effective contraception (%) <sup>3</sup>	0.15		150	0.12		160	0.774	308	0.4397	
Number of times (mean)	0.2	0.1	150	0.3	0.2	160	5.511	308	0.0000	
Notes: Please enter data in the yellow highlighted cells only. Please convert all yes/no responses to yes = one and no = zero in your datafile.										
All binary outcomes should be entered as decimals in the spreadsheet (e.g. 45% should be entered as 0.45). For all "number of times measures," impute cases that skipped out because they had not had sex/gotten someone pregnant/etc to zero in the numerator so that the measure represents the full sample.										
Please construct this variable, or a similar one, from the data. The percentages should sum to 100 percent. A chi-sq statistic is calculated for this variable (provided there are no rows with zero totals).										
<sup>1</sup>										
<sup>2</sup>	Impute those who have never had sex as zeroes in numerator.									
<sup>3</sup>	Impute those who did not have ever or did not have sex in prior 3 months as zeroes in numerator.									

## EXHIBIT L: ANALYSIS PLAN TEMPLATE and SUPPORTING TABLES

### 1) Research Questions That Address Program Effectiveness on Behavioral Outcomes

- a. **Primary research question(s):** Each primary research question should focus on the effect of the program on at least one behavioral outcome measure relevant to the HHS Evidence Review using the full analytic sample (unless the study has adequate power to test impacts for particular subgroup – e.g. sexually inexperienced at baseline) at a specific time point. The outcome(s) and the time point(s) should be clearly connected to the program’s logic model for the theory of change. For example:

“What is the impact of [treatment] relative to [counterfactual] on sexual activity and one year after the end of the treatment?”

- b. “What is the impact of [treatment] relative to [counterfactual] on risky sexual behavior one year after the end of the intervention?” **Secondary research question(s):** These research questions can focus on three possible impact questions:

- i. Impacts for subgroups
- ii. Impacts on the primary outcomes at different time points (such as immediately at the end of the treatment and/or 6-months later)
- iii. Impacts on other behavioral outcomes relevant to the evidence review which may not be considered a primary, intended outcome of the intervention.

### 2) Description of the Intervention and Counterfactual Condition

- a. **Intervention condition:** Describe the *intended* experiences of those in the intervention condition. In particular, describe the following.
  - i. **Intended program components:** Group sessions, individual services, etc.
  - ii. **Intended program dosage:** What is the total *intended* program dosage? How is that dosage acquired? How many sessions of what length, how frequent are they, and over what period? (e.g. “This is a 6 month program, with sessions occurring 3x/week for 30 minutes per session”).
  - iii. **Intended program content:** What is the intended program content and materials?
  - iv. **Intended program delivery:** Where is the program intended to be delivered? By whom? What are the intended characteristics of the program providers? What training and technical assistance is intended to be offered?
- b. **Counterfactual condition:** Describe the intended experiences of those in the counterfactual condition. If an alternative program is being provided to the

control/comparison group (e.g., there is not a “no treatment/business as usual” counterfactual condition), describe:

- i. **Intended program components:*** Group sessions, individual services, etc.
- ii. **Intended program dosage:*** What is the total *intended* program dosage; how many sessions of what length, how frequent are they, and over what period?
- iii. **Intended program content:*** What is the intended program content and materials?
- iv. **Intended program delivery:*** Where is the program intended to be delivered? By whom? What are the intended characteristics of the program providers? What training and technical assistance is intended to be offered?

### 3) Study Design

- a. **Sample formation:** Describe the ways in which the members of the target population become members of the impact study sample (used to answer the impact study research questions above). *Note: do not include a description of youth that were never intended to be part of the evaluation sample; for example, youth involved in program pilots.* Include information on:
  - i. **Eligibility criteria for target population:*** What characteristics are necessary for sample inclusion (e.g. age, gender, pregnant, geography, school enrollment, class enrollment, etc.)?
  - ii. **Purposeful Sampling:*** Describe any additional criteria for selecting the sample beyond the eligibility criteria (e.g. willingness to participate in the study for schools, not requiring ESL or other academic support for individuals).

*Note: this information has previously been described in the top box of the CONSORT diagram required for annual progress reports.*

#### b. **If a quasi-experimental design: Research group formation**

- i.* Describe the criteria used to determine whether individuals (or groups of individuals) would be assigned to the treatment or the comparison group, and the process used for constructing the treatment and comparison groups. When did this assignment procedure occur, relative to the timing of consent and baseline data collection?

#### c. **If a random assignment design: Random assignment process**

- i.* What is the unit of randomization (e.g. schools, classrooms, individuals, etc.)?
- ii.* Who conducts random assignment, when, and under what circumstances?
  - 1. Is randomization conducted by evaluation staff or by program staff?

2. When does random assignment occur with respect to the timing of consent and baseline data collection? For clustered randomized controlled trials (CRCTs), who was told of the outcomes of random assignment and for what purposes?
  3. Is randomization conducted all at once (meaning a large number of units is randomly assigned at a single point in time) or on a “rolling” basis (meaning, small numbers of units are randomly assigned at different points in time)? Describe the details of this process.
- iii.* Describe any stratification/blocking that is used to cluster units into groups before random assignment, or any variables used to match treatment units prior to assignment.
1. Describe how single units that could not be paired/blocked with others are assigned to condition.
- iv.* If applicable, describe any sub-sampling that occurred after random assignment, the reason for the sub-sampling, the criteria used for sub-sampling, and how the sub-sampling was operationalized.
- v.* Report the intended probability of assignment to the treatment group and whether that probability varies systematically (for example, across blocks/strata).
- d. **Consent process:** Describe, in detail, the consent process for both the treatment and control groups. Include in your descriptions similarities and differences with respect to timing, process, and materials used (like the consent forms, incentives, etc.).
- e. **Data collection:** Describe the sources of data to be used in the analyses. Describe the number of timing of each data collection point (e.g., baseline and the follow-up time periods used for primary and secondary research questions). Describe the modes and methods of collecting data at each data collection point (baseline and all follow-ups). Include a thorough description of the process and the timing for data collection, by study condition. Clearly articulate similarities and differences across the two study conditions.
- f. **Outcome measures:** Describe the outcome measures used to answer the primary (and secondary, if applicable), research questions, including the source. If the measures will be constructed measures of sexual risk behavior, include a description of what survey items will be used to create each construct.
- i.* Complete Table 1, describing all measures that will be used to answer the primary research questions assessing the impact of the program. Include the time periods that will be used to assess impacts for primary and secondary research questions.
  - ii.* Complete Table 1a for all measures that will be used to answer secondary research questions.

## 4) Analysis

- a. **Data cleaning:** Describe the ways in which data will be cleaned and prepared for analysis.
- b. **Assessment of baseline equivalence:** What measures will be used to examine the equivalence of the groups at baseline? What methods will be used to test the significance of the difference between the groups? *At a minimum, include the demographic and behavioral measures assessed in your annual reporting to OAH, as well as baseline measures of each outcome.*
- c. **Analytic approach for primary research questions:** Describe how the analysis will be conducted to answer the primary research questions, under an intent-to-treat (ITT) framework.
  - i. **Analytic sample:** Describe how the analytic sample will be defined. Describe how analysis will pool data across multiple sites or cohorts (if applicable).
  - ii. **Model specification:** Provide the model that will be used to estimate program impacts for each primary and secondary research question (logistic regression, etc.).
    1. What statistical software package will be used?
    2. Define the criteria that will be used to assess the statistical significance of study findings (for purpose of HHS Evidence Review, findings are considered statistically significant based on  $p < .05$ , two-tailed test).
    3. How will model adjust for clustering (if applicable)?
  - iii. **Covariates:** List all potential covariates that will be included in the analysis in Table 2 and justify your reason for their inclusion. If covariates have not yet been determined, describe a plan for determining what covariates will be included. Aside from the baseline version of the outcome of interest, will there be any covariates that will differ across the models used to answer the primary research questions? When appropriate, describe how blocking/stratification variables will be incorporated as covariates.
  - iv. **Missing data approach:** How will the analysis handle missing outcome data? How will the analysis handle data missing on any of the covariates indicated above?
  - v. **Sample weights:** Will sample weights be used? If so, what weights will be used? Why? How will they be constructed?
  - vi. **Adjustments for multiple comparisons (if applicable):** Describe the approach that will be used to adjust for the multiple hypotheses tests if more than one primary research question will be addressed. Or justify why a

multiple comparison adjustment will not be used in the case where multiple hypothesis tests will be conducted.

- vii. **Sensitivity analyses:** Describe any analyses that will be conducted to test the robustness of the results or the appropriateness of the analytic model for the observed data.
- d. **Analytic approach for secondary research questions:** Describe the analytic approach that will be used to address all secondary research questions. Please cover 4.b.i. – 4.b.viii above.

## 5) Plans for Presentation of results

- a. **Provide empty table shells of how findings will be presented to demonstrate the following key components of the analysis.**
  - i. **Sample flow:** The table shell must provide counts of sample members who contribute both a baseline and a follow-up survey, as well as tests of significance of the differences in various response rates. *See Table 3.*
  - ii. **Non-response analysis:**
    1. **Characteristics by response status:** This table shell must provide baseline characteristics of youth according to whether or not they completed a follow-up survey. *See Table 4.*
    2. **Characteristics of the baseline sample:** This table shell must provide descriptive statistics of the initial sample members who completed a baseline assessment on demographics and baseline measures of the outcomes of interest. *See Table 5.*
  - iii. **Baseline equivalence of analysis sample:** This table shell must contain descriptive statistics of the analysis sample (i.e. the sample members who were observed at the focal follow-up assessment period who may or may not have completed a baseline assessment) at baseline on demographics and baseline measures of the outcomes of interest. *See Table 6.*
  - iv. **Program impacts:** This table shell must contain descriptions of follow-up means and program impacts, including information on statistical significance of the difference. *See Table 7.*

## 6) Additional planned analyses.

Identify all additional research questions that you plan to address using data from this evaluation. These questions may include impacts on non-behavioral outcomes (such as knowledge and/or attitudes) and exploratory (non-experimental) analyses on mediator variables, dosage/participation, and the relationship between implementation and impacts. In



addition, this section can include alternate specifications used to test impacts of the intervention across time points, such as growth-curve analyses.

## Appendix Table Shells:

**Table 1. Behavioral outcomes used for primary impact analyses research questions.**

Outcome name	Description of the outcome, including how it is operationalized (e.g. "The outcome is a yes/no response taken directly from the survey" or "the risk outcome is calculated as the average of the five risk indicator variables").	Source of the measure (e.g. performance measure)	Timing of measure (e.g., 6 months after program ends)

**Table 1a. Behavioral outcomes used for secondary impact analyses research questions.**

Outcome name	Description of the outcome, including how it is operationalized (e.g. "The outcome is a yes/no response taken directly from the survey" or "the risk outcome is calculated as the average of the five risk indicator variables").	Source of the measure (e.g. performance measure)	Timing of measure (e.g., 6 months after program ends)

**Table 2. Covariates included in impact analyses**

Covariate	Description of the covariate and how it will be used as a covariate in the analysis.

**Table 3. Cluster and Youth Response Rates by Treatment Status**

	Period of time for the given event	All Students	Treatment	Control	T/C Difference	p-value
<b>Number of Clusters (if applicable)</b>						
(c1) In study at random assignment					NA	NA
(c2) Still in study at follow-up					NA	NA
<b>Cluster retention rate [(c2)/(c1)]</b>		NA			NA	NA
<b>Number of Youth:</b>						
(1) In study sites at random assignment <sup>a</sup>					NA	NA
(2) who consented					NA	NA
(3) Still in study at follow up					NA	NA
(4) who consented					NA	NA
(5) Completed a baseline survey					NA	NA
(6) Completed a follow-up survey					NA	NA
(7) Completed both baseline and follow-up surveys					NA	NA
<b>Response Rates Among Youth:</b>						
<b>Baseline Survey</b>						
In study sites at random assignment [(5)/(1)]		NA				
who consented [(5)/(2)]		NA				
who completed a follow-up survey [(7)/(6)]		NA				
		NA				
<b>Follow-Up Survey</b>						
In study sites at random assignment [(6)/(1)]		NA				
who consented [(6)/(2)]		NA				
		NA				
Still in study at follow up [(6)/(3)]		NA				
who consented [(6)/(4)]		NA				

<sup>a</sup> In cluster RCTs where cluster level attrition occurred, this number (and subsequent numbers in this section of the table) should reflect the number of students in non-attributing clusters.

**Table 4. Baseline Characteristics of Youth by response status**

Characteristic	All Youth Who Completed a Baseline Survey			
	Not Missing Outcome Data		Missing Outcome Data	
	Mean (or proportion)	Standard Deviation	Mean (or Proportion)	Standard Deviation

Note: Table 4 contains information for all students who completed a baseline survey.

**Table 5: Pre-treatment sample sizes and characteristics for the BASELINE sample**

Baseline measures	Treatment Group			Control Group			Baseline Differences		
	Unit of analysis (Table 4, Row 5)	Mean (or proportion)	Standard deviation (if applicable)	Unit of analysis (Table 4, Row 5)	Mean (or proportion)	Standard deviation (if applicable)	Mean difference	ICC (If applicable)	<i>p</i> -value of difference
Measure 1									
Measure 2									
Measure 3									

Note: Table 5 contains information for the BASELINE sample at BASELINE.

**Table 6: Pre-treatment sample sizes and characteristics for the ANALYSIS sample**

Baseline measures	Treatment Group			Control Group			Baseline Differences		
	Unit of analysis (Table 4, Row 6 or 7)	Mean (or proportion)	Standard deviation (if applicable)	Unit of analysis (Table 4, Row 6 or 7)	Mean (or proportion)	Standard deviation (if applicable)	Mean difference	ICC (If applicable)	<i>p</i> -value of difference
Measure 1									
Measure 2									
Measure 3									

Note: Table 6 contains information for the ANALYSIS sample at BASELINE.

**Table 7: Post-treatment outcomes and effects for the ANALYSIS sample**

Outcome Measures	Treatment group		Control Group		Estimated Effects		
	Mean (or proportion)	Standard Deviation (if applicable)	Mean (or proportion)	Standard deviation (if applicable)	Mean difference	ICC (if applicable)	<i>p</i> -value of difference
Measure 1							
Measure 2							
Measure 3							

Note: Table 7 contains information for the ANALYSIS sample at Posttest.